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No. 09-

IN THE

# Supreme Court of the United States

MEDELA AG and MEDELA, INC.,

*Petitioners,*

—against—

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., and WAKE FOREST UNIVERSITY HEALTH SCIENCES,

*Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

To qualify for patent protection, a claimed invention must constitute "non-obvious subject matter." 35 U.S.C. § 103. This Court has long held that "[t]he ultimate judgment of obviousness is a legal determination." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). Under Federal Circuit precedent, however, a person accused of patent infringement has no right to independent judicial, as distinct from lay jury, determination of obviousness. Rather, the Federal Circuit has held that a jury may render a verdict on the ultimate issue of obviousness, and that court review of such a verdict is limited to (i) "recreating" facts that "may have been found" by the jury in reaching its legal conclusion of obviousness, and then (ii) inquiring whether there was any permissible legal rationale that the jury might have adopted in reaching its legal conclusion of obviousness. Federal Circuit precedent on this point conflicts with two en banc decisions of regional circuit courts.

The question presented is:

Whether a person accused of patent infringement has a right to independent judicial, as distinct from lay jury, determination of whether an asserted patent claim satisfies the "non-obvious subject matter" condition for patentability.

## RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, Petitioners identify Medela Holding AG and Olle Larsson Holding AG as parent corporations.

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Medela AG and Medela, Inc. hereby petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this action.

## OPINIONS BELOW

The opinion of the Court of Appeals is reported at 554 F.3d 1010 and is reproduced in Appendix A. The jury verdicts relevant to this Petition are reproduced in Appendix B. The final judgment of the District Court is reproduced in Appendix C. The District Court's opinion denying Petitioners' renewed motion for judgment as a matter of law is unreported and is reproduced in Appendix D.

## JURISDICTION

The final judgment of the Court of Appeals was entered on February 2, 2009. A petition for rehearing was timely filed on February 17, 2009, and was denied on March 31, 2009. By Order dated June 22, 2009, this Court extended Petitioners' time to file a petition for a writ of certiorari to and including August 13, 2009. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

The district court had jurisdiction to hear this action under at least 28 U.S.C. § 1338(a). The Federal Circuit had jurisdiction to hear Respondents' appeal and Petitioners' cross-appeal under 28 U.S.C. § 1295(a)(1).

## STATUTORY PROVISION INVOLVED

35 U.S.C. § 103(a) prescribes the "non-obvious subject matter" condition for patentability. The text of this section is reproduced in Appendix E.

## STATEMENT OF THE CASE

One of the most important conditions for patent validity is the requirement set forth in 35 U.S.C. § 103(a) that a claimed invention must have been "non-obvious subject matter" at the time of its making by a patent applicant. *See* Robert P. Merges and John F. Duffy, *Patent Law and Policy* 611-12 (4th ed.

2007) (describing nonobviousness as "the ultimate condition of patentability" and "the final gatekeeper of the patent system") (internal quotations omitted). This case presents the question whether a person accused of patent infringement has a right to independent judicial, as distinct from lay jury, determination of whether an asserted patent claim satisfies that condition for patentability.

The "non-obvious subject matter" condition in § 103 was first codified by Congress in 1952 and first interpreted by this Court in the seminal case of *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *Graham* held that "the ultimate question of patent validity is one of law," *id.* at 17, and was to be "determined" by reference to "several basic factual inquiries" including "the scope and content of the prior art," the "differences between the prior art and the claims at issue," and "the level of ordinary skill in the pertinent art." *Id.*

The *Graham* Court described its opinion as "focus[ing] attention on the *appropriate standard to be applied by the courts*," *id.* at 18 (emphasis added), and stated "that the inquiry which the Patent Office and *the courts must make as to patentability* must be beamed with greater intensity on the requirements of § 103." *Id.* at 19 (emphasis added). Furthermore, the Court described the *Graham* litigation in the lower courts as "present[ing] a *conflict between two Circuits* over the validity of a single patent." *Id.* at 4. These and other statements in the *Graham* opinion strongly suggested that judges, not juries, were required to undertake the complex weighing and balancing of factors that answered "the ultimate question of patent validity" as "one of law." *Id.* at 17.

In subsequent cases interpreting the nonobviousness requirement of § 103, this Court reiterated that the "ultimate test of patent validity is one of law," *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 280 (1976), and repeatedly engaged in independent assessments of whether subject matter claimed in a patent was properly deemed "non-obvious subject matter." *See,*

*e.g.*, *Dann v. Johnston*, 425 U.S. 219, 230 (1976) ("The gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art"); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63 (1969) ("We conclude further that to those skilled in the art the use of the old elements in combination was not an invention by the obvious-nonobvious standard."); *United States v. Adams*, 383 U.S. 39, 51 (1966) ("We conclude the Adams battery was also nonobvious."). In all of these cases the Court identified the relevant prior art and engaged in complex reasoning and analysis en route to reaching its judgment. In none of these cases did the Court suggest that juries, rather than judges, could properly determine whether an asserted patent claim satisfied the § 103 condition as a legal matter.

The extent to which judges, rather than juries, were required to determine obviousness under 35 U.S.C. § 103 was such an important issue that two regional circuit courts adjudicated the issue in en banc decisions before intermediate appellate jurisdiction in patent cases was centralized in the Federal Circuit in 1982. *See Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1341-44 (7th Cir. 1983) (en banc); *Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647, 651 (9th Cir. 1982) (en banc) (per curiam). The Seventh and Ninth Circuits both held, en banc, that judges must independently determine whether proven facts lead to a legal conclusion of obviousness.

Starting in October 1982, appeals from judgments in civil actions "arising under" federal patent law were diverted from the regional circuits to a then newly-created intermediate appellate court, the Court of Appeals for the Federal Circuit. In sharp contrast with Seventh and Ninth Circuit precedent, the Federal Circuit took the position that lay juries can render verdicts that *preclude* independent judicial determination of the ultimate question of patent validity under § 103. Such jury verdicts typically take the form of simple "yes" or "no" answers to ques-

tions whether an asserted patent claim is invalid for obviousness.

Recognizing that a legal conclusion of obviousness or nonobviousness may rest on myriad different combinations of underlying historical facts and widely varying legal rationales, Federal Circuit precedent holds that post-trial or appellate review of a jury's verdict on the ultimate question of obviousness entails "*re-creating* the facts as they *may have been found* by the jury," and determining whether such hypothetical facts would be sufficient to support a legal conclusion of validity on *any* theory. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001) (emphasis added).

The present case well illustrates the operation of the Federal Circuit's approach and its practical effect, which is to eliminate any requirement that valid reasoning or analysis underlie a legal determination of obviousness or nonobviousness in patent litigation.

### A. District Court Proceedings

In August 2003, Respondents sued Petitioners for alleged infringement of two patents that disclosed allegedly novel apparatus and methods for treating wounds by applying negative pressure to the wounded area. Respondents demanded trial by jury of all issues so triable. Petitioners denied infringement, pleaded affirmative defenses, and counterclaimed for a declaratory judgment that the asserted claims of Respondents' patents were invalid.

Following nearly three (3) years of pretrial proceedings, the case was called for jury trial. At the conclusion of the Respondents' evidence, Petitioners moved for judgment that the asserted claims were invalid under § 103 as a matter of law. The motion was denied. Petitioners then introduced evidence in support of their defense of invalidity and their counterclaim seeking a declaratory judgment of invalidity.

At the conclusion of all the evidence, the district court provided the jury with lengthy instructions that stated in part:

> In determining whether or not these claims would have been obvious, you should make the following determinations:
>
> First, what is the scope and content of the prior art?
>
> Second, what differences, if any, are there between the invention of the claims of the patents and the prior art?
>
> Third, what was the level of ordinary skill in the art at the time the invention was made?
>
> Fourth, are there any objective indications of non-obviousness?
>
> Against this background, you must decide whether or not the invention covered by the claims in this case would have been obvious.

The jury was further instructed that its "determinations" of the above-identified matters were in turn dependent on various subsidiary legal conclusions. With regard to "the scope and content of the prior art," the jury was instructed that (i) as to certain "documents and events, you will be required to determine whether such documents or events *qualify* as prior art"; (ii) "you should determine *what is disclosed* in the prior art"; and (iii) "[y]ou must decide whether this prior art *was reasonably relevant* to the particular problem the inventor faced in making the invention covered in the patent claims." (Emphasis added.)

With regard to "the level of ordinary skill in the art at the time the invention was made," the jury received instructions on (iv) the circumstances in which a claimed "invention" may be deemed to have been "made"; and (v) "[f]actors to consider in determining the level of ordinary skill in the art."

With regard to "objective indications of non-obviousness," the jury was instructed that "you must consider certain factors which, if established, *weigh* in favor of finding that the invention would not have been obvious." (Emphasis added.) The "factors" so identified included (vi) "whether the invention was commercially successful;" (vii) "whether the invention satisfied a long-felt need in the art;" and (viii) "whether the invention was copied by others in the art."

Finally, the district court propounded jury interrogatories that called for "yes" or "no" answers to the following questions:

> Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '643 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 17, please refer to pages 25-34 and 38-45 of the Court's Instructions.
>
> Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '081 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 18, please refer to pages 25-34 and 38-45 of the Court's Instructions."

The jury provided thirty-seven (37) "no" answers to the questions quoted above (one answer for each patent claim asserted). *See* Appendix B hereto.[1] The

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[1] The jury also found that Respondents had failed to prove infringement of the asserted patents; however, notwithstanding the finding of non-infringement, the

**Footnote continued**

jury was not asked to provide, and did not provide, any explanation of these "no" answers. It is quite literally impossible to determine what facts the jury considered to have been proved, or not proved, by Petitioners relevant to their counterclaim of invalidity under 35 U.S.C. § 103(a), or what process of reasoning led the jurors to reach their "no" answers.

Based on the jury's verdict, the district court issued a final judgment that Petitioners "take nothing on their counterclaims against the Plaintiffs for declarations of patent invalidity and patent unenforceability." *See* Appendix C hereto. The district court did not provide any reasoning or analysis in support of this judgment.

Petitioners then renewed their motion for judgment as a matter of law. Still, the district court declined to make any independent determination of the issue of obviousness. Applying Federal Circuit precedent, the district court stated (*see* Appendix D):

> Applying the legal standards and upon review of the briefing, the Court finds sufficient evidence to justify the jury's verdict and thus declines to disturb it. The Court finds merit in Plaintiffs' credibility arguments. It is the province of the jury – not the judge – to determine the credibility of witnesses. In such a case as this, wherein highly qualified and devoted counsel represent both sides through a lengthy trial, jurors must wrestle with the credibility

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**Footnote continued from previous page**

district court retained jurisdiction to determine the merits of the Petitioners' counterclaim for patent invalidity. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96-97 (1993).

> of lay and expert witnesses alike, whose juxtaposed opinions are often equally possible but entirely diametric. As such, while it may be true that Defendant Medela provided arguably ample evidence of patent invalidity, such evidence carries only the weight as measured by a pool of dedicated jurors.

### B. Federal Circuit Proceedings

Petitioners timely appealed to the Federal Circuit from the district court's judgment that they "take nothing" on their counterclaim against Respondents for a declaratory judgment of invalidity under 35 U.S.C. § 103(a). Petitioners argued that the district court erred by "fail[ing] to make its own legal determination of obviousness," by "treat[ing] the obviousness conclusion as a pure factual question," and by "merely h[o]ld[ing] that the jury could reasonably have relied on the testimony of KCI's expert and rejected Medela's expert." Pet. C.A. Br. at 54.

In reviewing the district court's judgment on this issue, the Federal Circuit stated that "[t]he scope and content of the prior art are factual questions to be determined by the jury," App. at 17a, but because the jury in this case made no findings on those matters, the Federal Circuit applied its highly deferential standard of review: "This court reviews these factual determinations, 'whether explicit *or implicit within the verdict*, for substantial evidence.'" *Id.* (quoting *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001)) (emphasis added).

The phrase "implicit within the verdict" does not, in this context, connote factual findings that a jury must actually and necessarily have made, but rather refers to *hypothetical* factual "findings" that a jury *might* (or might not) have made. *See Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1304 (Fed. Cir. 2005) ("In re-creating the facts as they *may*

*have been found* by the jury, and in applying the *Graham* factors to the evidence of record in this case, we assess the evidence in the light most favorable to the verdict winner.") (quoting *McGinley*, 262 F.3d at 1351) (emphasis added).

Applying this standard, the panel majority cited disputed testimony that prior art references, including printed publications, purportedly "did not teach or suggest 'treating a wound with negative pressure,'" App. at 19a, and concluded: "we *must assume* that the jury found that the prior art does not disclose 'treating a wound with negative pressure' within the meaning of the patents." App. at 20a (emphasis added). Whether the jury *actually* made any such finding in this case, or utilized legal reasoning that was similar to that utilized by the panel below, is impossible to know or to determine.

For all of the time and money that went into developing and presenting proofs on the legal issue of patent validity in this case, no court has ever, to this day, made any independent determination of that issue.

## REASONS FOR GRANTING THE PETITION

Federal Circuit precedent broadly and improperly abrogates any right to independent judicial, as distinct from lay jury, determination of whether an asserted patent claim satisfies the nonobviousness requirement of 35 U.S.C. § 103(a).

Federal Circuit precedent on this point –

• conflicts with two en banc decisions of other circuits, both of which were unanimous in rejecting the very sort of jury procedure that was used in this case and in many other cases. (*See* Part I, *infra*.)

• conflicts with, or is in deep tension with, this Court's precedents on obviousness, which have repeatedly described obviousness as "a legal determination," *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007), stated that obviousness analysis was to be conducted by "a court, or patent examiner" (*id.* at

407), and instructed that "this analysis should be made explicit" so as "[t]o facilitate review" (*id.* at 418). (*See* Part II, *infra.*)

• is difficult or impossible to reconcile with settled principles of federal administrative law, under which the power to "pass on the validity of an administrative order" is reserved exclusively to courts, not juries, even in actions where a right to trial by jury exists and the invalidity of the administrative action is a legal defense to the action. *See Cox v. United States*, 332 U.S. 442, 453 (1947). (*See* Part III, *infra.*)

As shown by numerous objective indicators (discussed in Part IV, *infra*), the existence and extent of a litigant's right to independent judicial, as distinct from lay jury, determination of patent claim validity under 35 U.S.C. § 103 is a question of broad and general importance. Not only have two circuit courts thought the issue important enough to have it resolved through en banc decisions, but this Court previously granted certiorari on the closely related (though more narrow) issue of whether a patentee has a right to trial by jury in a civil action seeking a declaratory judgment of patent invalidity. *See Am. Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995). That case, however, was rendered moot after the respondent patentee dropped his jury demand, *see* 515 U.S. 1182 (1995), *vacating* 50 F.3d 966 (Fed. Cir.).

A federal study on reform of the patent system has identified excessive reliance on juries as "a serious threat to the patent system" and has singled out the use of juries in deciding validity issues as the area generating the greatest amount of public concern. The issue has also sparked a fierce and vigorous debate among commentators, many of whom have sharply criticized the use of juries for deciding patent validity issues.

Finally, the question presented here also fits squarely within the type of matters on which this

Court has seen fit to exercise its certiorari power in Federal Circuit patent cases.

## I. THERE IS AN ACKNOWLEDGED CIRCUIT SPLIT.

In *Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647 (9th Cir. 1982) (en banc), the court ruled that, because obviousness is a question of law, "[t]he court must, in all cases, determine obviousness as a question of law independent of the jury's conclusion." *Id.* at 651. The jury's role under *Sarkisian* is limited to, at most, (i) finding predicate facts through "detailed special interrogatories," *id.* at 650, and (ii) providing a "nonbinding advisory opinion" on obviousness that a court may use "for guidance." *Id.* at 651.

The Federal Circuit has repeatedly acknowledged that its precedent conflicts with the Ninth Circuit's en banc *Sarkisian* decision. In *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 895 n.5 (Fed. Cir. 1984), the Federal Circuit pointedly criticized *Sarkisian*, stating that "[t]he view suggested in *Sarkisian*, that a jury verdict on nonobviousness is at best advisory, would make charades of motions for directed verdict or JNOV under Fed.R.Civ.P. 50 in patent cases."

*Perkin-Elmer* rejected the Ninth Circuit's view that the courts must "determine nonobviousness 'independently' of the jury's verdict," *id.* at 895 (quoting *Sarkisian*), and instead held that, in reviewing a jury's verdict on the legal issue of obviousness, the "appropriate question" to be asked by a reviewing court is: "can the jury's *presumed findings* support [a] conclusion of nonobviousness encompassed in the jury's *verdict of validity*?" *Id.* (emphasis added).

The Federal Circuit's rejection of *Sarkisian* was again made clear in *Richardson* v. *Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989). In that case, the district court for the Central District of California followed the Ninth Circuit's rule from *Sarkisian*: The district judge had used an "advisory" jury verdict on obviousness and had "independently decided" the va

lidity questions presented in the case, including obviousness. *Id.* at 1234. Though the jury and district judge were in agreement on the outcome, the Federal Circuit went out of its way to describe the *Sarkisian* procedure as "this discredited procedure of advisory verdicts," and specifically stated that "[i]t is established that the jury may decide the questions of anticipation and obviousness, either as separate special verdicts or en route to a verdict on the question of validity, which may also be decided by the jury." *Id.* To support that proposition, the court set forth a long string cite exclusively devoted to Federal Circuit precedents.

Petitioners in this case specifically argued to the Federal Circuit that "the district court erred by failing to conduct its own obviousness analysis." App. at 19a. In rejecting that argument, the Federal Circuit (consistently with its precedent) treated the jury's verdict on the ultimate question of obviousness as *precluding* independent judicial determination of the legal issue of obviousness, and as instead requiring a reviewing court to hypothesize "implicit" factual determinations (App. at 17a) and to "assume" that the jury adopted a permissible legal rationale. App. at 20a.

Not only is this procedure inconsistent with the Ninth Circuit's ruling in *Sarkisian*, but it purports to eliminate any requirement that valid reasoning or analysis underlie a legal determination of obviousness or nonobviousness. From the jury's "no" answers to questions whether "the Defendants [had] proven by clear and convincing evidence that the invention . . . [was] obvious" (*see* Appendix B), it is impossible to know what process of reasoning led to that legal conclusion or to review the correctness of that reasoning.

The jurors might have found facts sufficient to render the claimed inventions legally obvious but then erred in their analysis of obviousness (which is a difficult doctrinal area of patent law). Or the jury might have found nothing to be "clear" in a weeks-

long patent trial that concluded with pages of instructions on the legal tests of obviousness. But under the Federal Circuit rule applied below, a reviewing court is said to be required to "recreat[e] the facts as they *may have been found* by the jury," *Group One*, 407 F.3d at 1304 (quoting *McGinley*, 262 F.3d at 1351) (emphasis added), and then to apply a legal analysis that could be entirely different from whatever unstated and unknowable reasoning process might have underlain a jury's § 103 validity analysis.

This approach—treating a jury verdict on obviousness as requiring a court to hypothesize factual determinations and legal reasoning that may (or may not) have underlain the verdict—is also plainly inconsistent with the approach of the Seventh Circuit in *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324 (7th Cir. 1983) (en banc). There, as here, the district court had submitted the question of obviousness to a jury, and the jury had returned the answer, "We, the jury, find that the subject matter of the [patent in suit] was not obvious to one of ordinary skill in the art in the years 1963-64." *Id.* at 1328. The district court did not treat that jury verdict as merely advisory but instead, after "compos[ing] no findings of its own," issued judgment declaring that the patent was "good and valid in law." *Id.* at 1329 (quoting the district court's ruling).

The *Roberts* court condemned this procedure as "deficient in every respect" and ruled that "[t]he trial court abdicated its control over the legal issue [of obviousness]." *Id.* at 1342. Under the approach set forth in *Roberts*, jury verdicts can be given weight in obviousness analysis only if the jury has been asked to make findings on specific facts or if the trial judge has specifically instructed the jury that it must render a particular verdict "if it finds facts A, B, C, and D." *Id.* at 1341. On this point the *Roberts* en banc court was unanimous, for even Judge Posner (who dissented as to whether the particular patent was obvious) noted that "[a]ll of us agree that the ultimate question of obviousness is for the court, not

the jury, and that the jury's role is limited to deciding subsidiary fact questions, of the who-did-what-to-whom variety." *Id.* at 1347 (Posner, J., dissenting on other grounds).

The *Roberts* court also considered, and rejected, a split panel decision from the Fifth Circuit, *Control Components, Inc. v. Valtek, Inc.*, 609 F.2d 763 (5th Cir.), *reh'g denied*, 616 F.2d 892, *cert. denied*, 449 U.S. 1022 (1980), that endorsed a jury verdict review procedure that was virtually identical to what the Federal Circuit applied in this case. In *Control Components*, the district court instructed the jurors on the law of obviousness and then submitted to them the question whether the invention "would have been obvious to one of ordinary skill in the [relevant] art." *Id.* at 766-67. The Fifth Circuit then assumed that the jury "made implicit findings on each underlying factual inquiry," *id.* at 768, and affirmed the verdict on the ground that the jury's verdict was "supported by substantial evidence." *Id.* at 769.

In a partial dissent, Judge Rubin argued that the majority's position on this point was "a step further into the Serbonian bog that threatens to engulf patent litigation." *Id.* at 774. He noted that if the jury verdict on the ultimate legal issue is deemed to include "implicit findings on non-obviousness, then the trial court cannot review either the verdict or the underlying findings unless the standard for judgment notwithstanding the verdict is used." *Id.* at 775 (quoting Gary M. Ropski, *Constitutional and Procedural Aspects of the Use of Juries in Patent Litigation*, 58 J. Pat. Off. Soc'y 609, 685 (1976)). The result would be "that validity will 'effectively become a question for the jury, not one of law for the judge.'" *Id.* (quoting Ropski, *supra*).

The split panel in *Control Components* generated a dissent from denial of *en banc* rehearing in which Judge Brown, joined by three other judges, explained:

> This case is of exceptional importance because the issues it presents arise in every jury trial of a patent case. Submitting the obviousness issue to the jury for a general verdict, in the manner our previous decisions permit, appears to me to be inconsistent with the precept that "the ultimate question of patent validity is one of law." *Graham v. John Deere Co.* . . .

616 F.2d 892, 892 (5th Cir. 1980) (quoting *Graham*, 383 U.S. at 17).

Subsequently, in a unanimous panel decision authored by Judge Brown, *Baumstimler v. Rankin*, 677 F.2d 1061 (5th Cir. 1982), the Fifth Circuit described Judge Rubin's partial dissent in *Control Components* as "cogent and convincing" and ruled that, if the issue of obviousness were tried to a jury, the special interrogatories favored by Judge Rubin should generally be used to determine the factual predicates of obviousness. *Id.* at 1071-72. Trial judges who did not use such interrogatories, the court warned, would bear a "heavy burden of convincing the reviewing court that [they] did not abuse [their] discretion." *Id.* at 1072. The court noted that its agreement with Judge Rubin's position was motivated by the need to maintain "meaningful appellate review" over the legal issue of patent validity. *Id.*[2]

Thus, the issue presented in this petition engages a circuit split with at least two en banc regional cir-

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[2] Though the Seventh Circuit in *Roberts* expressly disagreed with the panel majority in *Control Components*, the court noted with approval that "Judge Rubin's viewpoint [in his partial dissent] has found favor in a subsequent Fifth Circuit decision." *Roberts*, 723 F.2d at 1342 n.24 (citing *Baumstimler*, 677 F.2d 1061).

cuits against the Federal Circuit's position. In addition, the Fifth Circuit either has an intra-circuit split or has moved into alignment with the circuits opposing the Federal Circuit position.

Although the Federal Circuit currently has exclusive intermediate appellate jurisdiction to hear appeals from final judgments in civil actions "arising under" federal patent law, *see* 28 U.S.C. § 1295(a)(1), this Court has continued to use circuit splits to identify which Federal Circuit patent cases merit a grant of certiorari. For example, in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), the petitioner argued, as one reason for granting certiorari, that the Federal Circuit had diverged from the approach taken by regional circuits prior to the creation of the Federal Circuit. *See* Petition for Writ of Certiorari, *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998) (No. 97-1130), 1998 WL 34081020, at *9-*10 & n.10. This Court granted certiorari and, in its opinion, specifically noted the circuit split as one factor justifying the court's grant of certiorari. *See Pfaff*, 525 U.S. at 60. Similarly, this Court granted certiorari in *KSR* where the petition for certiorari also relied on an acknowledged circuit split between Federal Circuit and regional circuit law. *See* Petition for Writ of Certiorari, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (No. 04-1350), 2005 WL 835463, at *20-*21.

Furthermore, in his concurrence in *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002), Justice Stevens stated that circuit splits remain helpful to this Court in identifying patent cases warranting a grant of certiorari. *See id.* at 839 (noting that a "conflict in [circuit] decisions [on patent law issues] may be useful in identifying questions that merit this Court's attention"). Justice Stevens also noted that "decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias." *Id.* Circuit splits engaging en banc decisions of the regional circuits should be especially helpful to this Court in making certiorari decisions

because the decision to consider the issue *en banc* provides an additional indication of importance.

## II. THE FEDERAL CIRCUIT'S APPROACH CONFLICTS WITH, OR IS IN DEEP TENSION WITH, THIS COURT'S PRECEDENTS ON OBVIOUSNESS.

Federal Circuit jury trial precedent is also difficult or impossible to reconcile with this Court's precedents on obviousness. For more than four decades, this Court has held that "the ultimate question of patent validity is one of law." *Graham*, 383 U.S. at 17. Moreover, in its recent *KSR* decision, this Court went beyond confirming, once again, that "[t]he ultimate judgment of obviousness is a legal determination," 550 U.S. at 427, but also stated multiple times that the obviousness analysis was to be conducted by courts or patent examiners, with no mention whatsoever of juries conducting the analysis. *See id.* at 407 ("If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103."); *id.* at 420 & 421 (describing the analysis conducted by "courts and patent examiners" under the case law on obviousness).

The *KSR* Court also instructed that "[t]o facilitate review, this [obviousness] analysis should be made explicit." *Id.* at 418. Not even the most elaborate of special jury verdict forms under Federal Rule of Civil Procedure 49 can yield an "explicit" "analysis" of whether or why subject matter claimed in an issued patent should or should not be deemed "non-obvious subject matter" as a legal matter. Yet under the Federal Circuit-sanctioned procedure that was applied in this case, the entire "analysis" of obviousness can consist of a jury's "yes" or "no" answer to the legal question whether an asserted patent claim was "proven" to have encompassed "obvious" subject matter by "clear and convincing evidence." Such a black box verdict hides all analysis and substantially thwarts effective review, because no one can be sure what reasoning process led the jury to its ultimate

legal conclusion of obviousness. *See* Kimberly A. Moore, *Juries, Patent Cases, & a Lack of Transparency*, 39 Hous. L. Rev. 779, 791 (2002) ("the Federal Circuit presumes that all of the jury's reasoning was correct unless there are no facts in the record that would have supported that verdict").

Here the jury was given about seven (7) pages of instructions on the patent law of obviousness (at least one full page of which was devoted mainly to listing the pieces of prior art to be considered). While six or seven pages of complex instructions on the law of obviousness may certainly seem lengthy to jurors having no educational background in law, the instructions are themselves *nothing more* than a nutshell's nutshell of the law in this area. One leading casebook on patent law devotes over 160 pages to the exposition of obviousness law. *See* Merges & Duffy, at 611-780. Even a leading summary of the law—one marketed merely as an introductory aid for law students—spends over twenty-five pages on obviousness law. *See* Janice M. Mueller, *Introduction to Patent Law* 167-194 (2006); *see also id.* at backcover (noting that the work is designed to be an "accessible" aid for "law students"). Another popular student aid spends over forty pages on the area. *See* Martin J. Adelman et al., *Patent Law in a Nutshell* 144-88 (2008).

Even with such books, law students are not supposed to learn patent obviousness law without engaging in significant study and without also receiving hours of classroom instruction. By contrast, under the Federal Circuit's authorized procedure, lay jurors with no legal training whatsoever are supposed to learn patent obviousness law on the basis of less than ten pages of text and, at most, a few minutes of oral instruction by the trial judge. The jurors' subsequent "yes" or "no" answers to legal questions are then used to hypothesize "implicit" factual findings and legal reasoning that may never, in fact, have existed. The entire procedure seems to be a polar opposite from the explicit and careful process of

legal analysis that *KSR* and this Court's earlier precedents have mandated that courts should follow in analyzing the legal issue of obviousness.

## III. THE FEDERAL CIRCUIT'S APPROACH IS DIFFICULT OR IMPOSSIBLE TO RECONCILE WITH SETTLED PRINCIPLES OF ADMINISTRATIVE LAW.

As this Court has previously recognized, "[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office." *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). The Patent Office (now renamed the Patent and Trademark Office or "PTO") is an administrative agency that is generally subject to standard principles of administrative law. *See Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). This Court has previously emphasized that, in light of "the importance of maintaining a uniform approach to judicial review of administrative action," the Federal Circuit must review the PTO under the same standards applied to other agencies. *Id.*

In other contexts involving court actions based on a predicate administrative action, litigants are permitted to raise the invalidity of the administrative action as a defense. This Court, however, has clearly stated that the validity of the agency's action is a matter for a court's independent judgment.

The leading case, *Cox v. United States*, 332 U.S. 442 (1947), involved a criminal prosecution for violating an administrative order authorized under the Selective Training and Service Act. The defendants in the case were Jehovah's Witnesses who had already been granted conscientious objector status. Conscientious objectors were, however, required by law to serve in civilian public service camps unless they could prove that they were "ministers," which would exempt them entirely from service. The defendants' claims to being ministers were rejected by local and appellate boards of the selective service system, and the defendants were ordered to report to public ser-

vice camps. The government criminally prosecuted the defendants after they either failed to go to camp or went to camp but then fled.

After deciding that the defendants could raise the invalidity of the administrative orders as a defense, this Court addressed whether the invalidity defense should be adjudicated by the judge or the jury. In his plurality opinion for four Justices, Justice Reed reasoned that "[t]he concept of a jury passing independently on an issue previously determined by an administrative body *or reviewing the action of an administrative body* is contrary to settled federal administrative practice." *Id.* at 453 (Reed, J.) (emphasis added). Justice Reed opined that "the constitutional right to jury trial does not include the right to have a jury pass on the validity of an administrative order." *Id.* On this point, Justice Reed's opinion appears to speak for the Court majority, for Justice Douglas's opinion (which was joined by Justice Black) expressly agreed with the four-Justice plurality opinion that the validity of the administrative order "is properly one of law for the Court" and "join[ed] in the opinion of the Court" on the issue. *Id.* at 455.

Nothing in *Cox* denies that judicial review of an administrative order may require some degree of factfinding. Indeed, Justice Reed specifically referred to the "analogous power of a judge as to admissibility," *id.* at 453 n.5, which of course includes the power to find facts necessary to rule on the point of law, *see id.* (citing precedents such as *Steele v. United States*, 267 U.S. 505, 510-511 (1925) and *Ford v. United States*, 273 U.S. 593, 605 (1927), which sustained the power of courts to find facts necessary to resolve admissibility disputes); *Gila Valley, Globe & N. Ry. Co. v. Hall*, 232 U.S. 94, 103 (1914) (holding that any "question of fact" necessary for an admissibility determination is "one to be determined by the trial court, and not by the jury").

Both of the leading commentators on administrative law from the mid-twentieth century recognized

*Cox* as standing for the general proposition that, in actions brought on the basis of an administrative order where the invalidity of the order is a proper defense, the court should "withhold[] from the jury the validity of the order." Kenneth Culp Davis, *Administrative Law Treatise* § 8.16, at 597 (West 1958); *see also id.* (noting that "seven Justices" agreed on this point in *Cox*). *See also* Louis L. Jaffe, *Judicial Control of Administrative Action* 394 (Little Brown 1965) (explaining *Cox* to mean that, even though the "validity of an administrative order depends on certain facts," those facts "need not be determined by a jury" because they go only to "the validity of the order," which is reserved for the court).

The case for jury participation is much weaker in the context of determining patent obviousness than it was in *Cox*. Not only did *Cox* involve a criminal prosecution, but the party seeking the jury trial right was trying to secure *greater* scrutiny of an administrative action. Here, by contrast, the party favoring the jury trial right (the patentee) is trying to sustain an administrative action. Because the jurors are instructed that they must presume that every allowed patent claim is valid and may reach a conclusion of invalidity only if "clear and convincing evidence" supports such a conclusion, giving preclusive effect to a jury's lay opinion on the legal issue of obviousness does not foster a firm check on governmental action by ordinary citizens but, to the contrary, tends to insulate PTO agency actions from effective judicial review.

*Cox* articulates a general norm applicable to judicial review of federal administrative action. The Federal Circuit's rule conflicts with that norm. In similar circumstances, this Court has previously granted certiorari in cases to review whether the Federal Circuit's patent jurisprudence has diverged from basic rules of law applicable in other areas.

For example, in *eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388 (2006), the Petition for Certiorari relied heavily on the divergence between the Fed-

eral Circuit's rules for granting an injunction in patent cases and the equitable rules governing injunctions in other areas of law. *See, e.g.*, Petition for Writ of Certiorari, *eBay v. MercExchange*, 547 U.S. 388 (2006) (No. 05-130), 2005 WL 1801263, at *13-*22. This Court granted certiorari, 546 U.S. 1029 (2005), and unanimously reversed on the ground that the injunction practice in patent cases must follow "the traditional four-factor framework that governs the award of injunctive relief" generally. 547 U.S. at 394.

Similarly, in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the Petition for Certiorari argued that the Federal Circuit's standards for permitting a declaratory judgment action in patent disputes had diverged from the more general standards applicable to declaratory judgment actions in other areas of law. *See* Petition for Writ of Certiorari, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (No. 05-608), 2005 WL 3067195 at *8-*16. The Court granted certiorari and also reversed, relying on declaratory judgment precedents from non-patent cases to overturn the Federal Circuit's precedents on the availability of declaratory judgment jurisdiction in patent cases. *See* 549 U.S. at 126-33.

Thus, divergence between general legal principles and Federal Circuit patent law precedents has in the past provided a compelling reason to grant certiorari (and, ultimately, to reverse the Federal Circuit). In this case, the conflict between the general principle of administrative law articulated in *Cox* and the Federal Circuit rule is merely one of many reasons to grant certiorari.

## IV. THE ISSUE IS IMPORTANT AND WORTHY OF THIS COURT'S ATTENTION.

Numerous objective indications demonstrate that the question presented by this Petition is an extremely important issue for the patent system.

1. *The Grant of Certiorari in Lockwood.* First, as discussed above, the issue has already provoked a

wealth of judicial opinions on the subject, including two en banc circuit court decisions, a dissent from denial of rehearing en banc in the Fifth Circuit, and a likely intra-circuit split in the Fifth Circuit. But perhaps the best gauge of importance is this Court's prior grant of certiorari in *American Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995) (No. 94-1660).

The *Lockwood* litigation was similar to this case in many respects. After the plaintiff brought a patent infringement action, the defendant raised patent invalidity as a defense and counterclaimed for a declaratory judgment of patent invalidity (as the Petitioners here did). *See In re Lockwood*, 50 F.3d 966, 968-69 (Fed. Cir. 1995). In *Lockwood*, however, the defendant won a summary judgment of noninfringment. The issue then became whether the plaintiff-patentee had a jury trial right on the defendant's counterclaim for a declaratory judgment of patent invalidity. The district court granted a motion to strike the patentee's jury demand. On a petition for writ of mandamus, the Federal Circuit reversed and ordered the district court to hold a jury trial on the invalidity defense.

Dissenting from the denial of rehearing en banc, Judge Nies (joined by Judges Archer and Plager) argued that the "mandamus order in this case creates the type of conflict with other circuits that warrants Supreme Court review." *Id.* at 987 (Nies, J., dissenting). Judge Nies then detailed the circuit split discussed above, citing the en banc *Sarkisian* and *Roberts* decisions and the long line of contrary Federal Circuit precedents (*id.* at 987-90), and stated: "It is my understanding that the denomination of an issue as one of law represents a policy decision that a judge is more appropriate than a jury to make the decision. As a matter of policy for reasoned and uniform decisions, this is true of patent validity." *Id.* at 990.

After certiorari was granted in *Lockwood*, the patentee withdrew his jury demand and moved for dismissal of the Supreme Court case as moot. The-

reafter this Court vacated the grant of certiorari, 515 U.S. 1182 (1995). The prior grant of certiorari provides a strong indication that the allocation of decisional power between judge and jury on patent validity issues is important enough to warrant this Court's attention. Indeed, this Court granted certiorari in *Lockwood* (i) even though the Petition for Certiorari was interlocutory; (ii) even though the case involved the unusual procedural posture where the defendant had won summary judgment as to all the plaintiff-patentee's infringement claims and the counterclaim for a declaratory judgment of invalidity was all that was left to be tried; and (iii) even though the Supreme Court phase of the litigation was always susceptible to being rendered moot if the patentee withdrew his jury demand (which was in fact what ultimately happened).

The present case has none of those procedural oddities. The case arises from review of a final judgment; it involves the more typical situation where infringement and patent validity are tried together; and it is not susceptible to being rendered moot by the Respondent merely withdrawing a jury trial demand. Judge Nies was absolutely correct in 1995 that the conflict between Federal Circuit and regional circuit precedent "warrants Supreme Court review." *Lockwood*, 50 F.3d at 987.

2. *The 1992 Report to the Secretary of Commerce.* In 1992, a final report on patent law reform was issued by a special Advisory Commission convened by the Secretary of Commerce and consisting of leading representatives from U.S. businesses, universities, the patent bar, and the public at large. *See* The Advisory Commission on Patent Law Reform: *A Report to the Secretary of Commerce* (1992). Even by the time of this report, the Commission observed that "the proportion of jury trials has exploded to the point where between thirty and fifty percent of all patent trials employ a jury as the fact finder" and noted that this "dramatic increase in the use of juries is generating concern in the patent user community

that juries are being used to avoid the substantive merits of a patent dispute." *Id.* at 107. (While the 30-50% jury trial rate measured in 1992 did represent an alarming explosion compared to historical rates, the rate has since risen much higher. *See* point 3, *infra*.)

Many members of the Commission worried that "a serious threat to the patent system could be developing" as the public might come to believe the results of patent trials "are little more than a throw of the dice." *Id.* at 109. Already, the Commission found that, "[w]ithout exception," members of the public commenting on the subject "felt that the problems were serious, that jury trials were 'getting out of hand,' and that the use of jury trials should be curtailed if possible." *Id.* at 108. Moreover, the Commission specifically found that "[m]ost of the negative comments were focused on the use of a jury to determine patent validity." *Id.*

The Advisory Commission ultimately "hope[d] that by raising this issue, other bodies will initiate the appropriate studies and debate." The courts in general and this Court in particular, have long played a dominant role in allocating decisional power between judges and juries. As will be shown below, debate on jury trials has now continued for years, and thus it is now an appropriate time for this Court to enter the debate.

3. *Recognition of Importance in the Academic Literature.* The secondary literature has repeatedly recognized the importance of the issue presented here and has detailed the negative consequences flowing from the Federal Circuit doctrine.

For example, Professors Jaffe and Lerner have written: "a dramatic change that has occurred on the CAFC's watch is an increasing reliance on juries in patent trials." Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress* 123

(Princeton 2004). The statistics are presented in the table below:

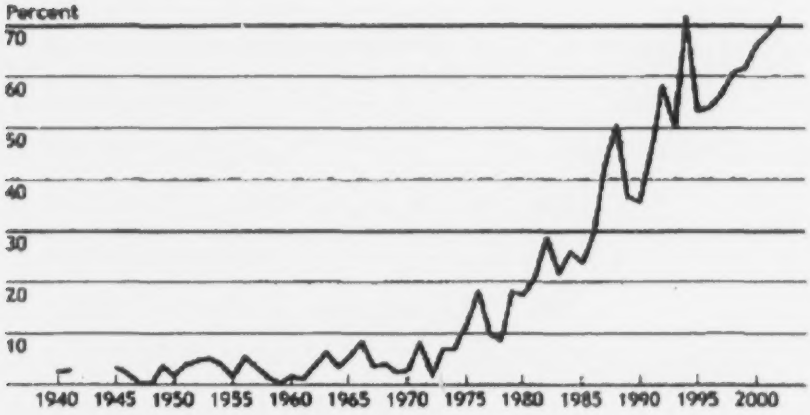


**Figure 4.4** Share of patent cases tried before juries.

Jaffe and Lerner further note that, even though both judges and litigants have long been skeptical of the ability of juries to decide complex patent cases rationally, "the CAFC has taken a relatively sympathetic view of juries" and "has stated that patentees have an absolute right to a jury trial on questions of patent validity." *Id.* at 124. Jaffe and Lerner also show that the bias in favor of juries over judges produces a pronounced pro-patentee tilt to the law, as statistics demonstrate that "juries are more sympathetic to patentholders than judges." *Id.* at 125.

The reasons are readily discernable why a pro-jury bias is also pro-patentee: The Federal Circuit has forcefully instructed trial judges (i) that they must "clearly instruct[] jurors to presume the patent is valid," *id.*; (ii) that the presumption of validity cannot be overcome except by clear and convincing evidence; and (iii) that this "presumption is *never* annihilated, destroyed, or even weakened, regardless of what facts are of record." *ACS Hosp. Sys., Inc. v. Montefiore Hosp.* 732 F.2d 1572, 1574-75 (Fed. Cir. 1984) (emphasis in original). Yet "the CAFC has

precluded the presentation to juries of information about the weaknesses and limitations of the patent examination process." Jaffe & Lerner, *supra*, at 124.

Thus, while judges familiar with administrative agencies in general and the PTO in particular might be more willing to take a more realistic view of the legal presumption of validity (as this Court did in *KSR*),[3] jurors may very well balk at second-guessing the action of an expert administrative agency, which comes to court clothed in a seemingly strong legal presumption of validity. Indeed, jurors may be quite rational to do so, for however faulty may be the judgment of the PTO, it might be better than that of jurors who are given seven pages of instructions and have no formal training on the patent law of obviousness. The solution to excessive juror deference to presumed administrative expertise is neither to give jurors more instructions on the foibles of administrative agencies nor to train them for a few weeks on the law of obviousness and patent validity. The solution is to recognize, as the Ninth Circuit did, that judges have the power and responsibility to review independently whether patents satisfy the statutory nonobviousness requirement.

As another commentator has recognized, the "increased use of juries and their expanded role in patent trials have clashed with a fundamental premise found in the legislation creating the Federal Circuit." Allan N. Littman, *The Jury's Role in Determining Key Issues in Patent Cases:* Markman, Hilton Davis *and Beyond*, 37 IDEA 207, 209 (1997). The legisla-

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[3] *See KSR*, 550 U.S. at 426 (invalidating a patent claim after noting "that the rationale underlying the presumption — that the PTO, in its expertise, has approved the claim — seems much diminished here" where the PTO had not considered the relevant prior art).

tion creating the Federal Circuit was generally thought to be needed to foster "nationwide uniformity in patent law" and to "make the rules applied in patent litigation more predictable." *Id.* at 210 (quoting legislative history of the legislation creating the court). Yet if "the application of basic doctrines of patent law are subsumed within jury verdicts, particularly general verdicts, uniformity, predictability and doctrinal stability could easily become hollow shells within which juries could do as they wished." *Id.*

The unpredictability introduced by jurors attempting to rule on legal issues such as obviousness is not good for the patent system. As Professor Jaffe has noted, "[h]aving decisions made by people who cannot really understand the evidence increases the uncertainty of the outcome. The combination of this uncertainty with the legal presumption of validity . . . is a big reason why accused infringers often settle rather than fight even when they think they are right." Adam B. Jaffe, *Patent Reform: No Time Like the Present*, 4 J. L. & Pol'y for Info. Soc'y 59, 72 (2008).

The secondary literature also shows that now is an excellent time to address the issue presented in this Petition. The persistence of the circuit split here makes it extremely unlikely that the lower courts will resolve the issue. Moreover, statements in this Court's recent *KSR* opinion have opened a vigorous debate about the continuing role of the jury in evaluating the nonobviousness of asserted patent claims. *Compare* Constantine L. Trela, Jr., *An Afterward to: A Panel Discussion on Obviousness in Patent Litigation:* KSR International v. Teleflex, 6 J. Marshall Rev. Intell. Prop. L. 633, 634 (2007) (asserting that the *KSR* decision suggests "that permitting the jury to decide the ultimate question of obviousness is wrong") *with* William F. Lee et al., *Reflections on the Ongoing Role of Juries in Determining Obviousness in Patent Cases After the Supreme Court's Decision in* KSR, 76 Patent, Trademark & Copyright

J. No. 1870, at 3 (BNA May 30, 2008) (arguing that "*KSR* would not seem to mandate any fundamental rethinking of the role of juries in determining obviousness").

Although the Federal Circuit now has jurisdiction over most patent appeals, this Court has frequently reviewed Federal Circuit patent decisions that "present an issue of the allocation of power among institutional actors." Mark D. Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001 U. Ill. L. Rev. 387, 409. *Cf. Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) (holding that "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court"). Such policing of institutional allocations of power is considered highly desirable even among those who otherwise advocate that this Court should "resist[] the temptation to speak directly on substantive doctrinal matters [of patent law]." Janis, *supra*, at 419.

Other commentators have also favorably remarked on this Court's apparent willingness to grant certiorari (i) to review "the allocation of decisional power within the patent system," John F. Duffy, *The* Festo *Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 Sup. Ct. Rev. 273, 340; (ii) "to bring patent related jurisprudence into conformity with rules applicable in other areas," Hon. Timothy B. Dyk, *Forward: Does the Supreme Court Still Matter?*, 57 Am. U. L. Rev 763, 769 (2008); or more generally (iii) "to prevent patent law from ossification and to ensure that appropriate policy considerations play a role in the development of the law." *Id.* at 763. *See also* John M. Golden, *The Supreme Court as "Prime Percolator": A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. Rev. 657, 720 (2009) (arguing that Supreme Court review of patent cases is desirable "in areas where Federal Circuit decisions may have unduly ossified the law").

This case presents all of these factors: It is a case about the allocation of decisional power; the Federal

Circuit's rule deviates from standard principles of administrative law; and the Federal Circuit's exclusive jurisdiction has led to an ossified rule that had previously been the subject of intensive en banc scrutiny by the regional circuit courts.

The question presented by this Petition has generated a pitched and vigorous debate that is now fully joined. It is ripe for a decision by this Court.

## CONCLUSION

For the reasons set forth above, this Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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# APPENDIX

# APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED FEBRUARY 2, 2009

## UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007-1340, -1341, -1342

KINETIC CONCEPTS, INC., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences,

Plaintiffs-Cross Appellants,

v.

BLUE SKY MEDICAL GROUP, INC.,

Defendant-Appellant,

and

RICHARD S. WESTON,

Defendant-Appellant,

and

MEDELA AG and MEDELA, INC.,

Defendants-Appellants.

*Appendix A*

Appeals from the United States District Court for the Western District of Texas in case no. 03-CV-0832, Judge W. Royal Furgeson, Jr.

DECIDED: February 2, 2009

Before BRYSON, DYK, and PROST, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* PROST. Dissenting opinion filed by *Circuit Judge* DYK.

PROST, *Circuit Judge.*

Defendants Medela, Inc. and Blue Sky Medical Group, Inc. appeal the denial of their motion for judgment as a matter of law on obviousness and their alternative motion for a new trial on obviousness. They also appeal the district court's claim construction and failure to declare several claim terms indefinite. Plaintiff Kinetic Concepts, Inc. cross-appeals the denial of its motion for judgment as a matter of law on infringement and its alternative motion for a new trial on infringement.

For the reasons set forth below, we affirm.

## I. BACKGROUND

Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences (collectively, "KCI") brought suit against Medela AG, Medela, Inc., Richard Weston, and Blue Sky Medical Group, Inc. (collectively, "Defendants"), alleging infringement of U.S. Patent Nos. 5,636,643 ("'643

patent") and 5,645,081 ("'081 patent"), as well as claims of false advertising, unfair competition, and conspiracy. Defendants responded with counterclaims alleging that the asserted patents were invalid and unenforceable. After a six week trial in the United States District Court for the Western District of Texas, the jury returned a verdict that the asserted patents were not shown to be invalid, unenforceable, or infringed. The jury also found against KCI on its false advertising, unfair competition, and conspiracy claims.

After trial, Defendants filed a motion for judgment as a matter of law ("JMOL") that the asserted claims are invalid as obvious under 35 U.S.C. § 103. In the alternative, Defendants requested a new trial on obviousness. KCI filed its own motion for judgment as a matter of law on infringement, or in the alternative, requested a new trial on infringement. The district court denied each of these motions.

Defendants now appeal the district court's denial of their JMOL motion on obviousness, arguing that under a proper claim construction no reasonable juror could have found that the prior art did not render the asserted patents invalid. In the alternative, Defendants ask us to order a new trial on obviousness because the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), effected a supervening change in the law that retroactively rendered the jury instructions on obviousness erroneous. They also appeal the district court's determination that "selected stage of healing," "reduction in bacterial density in the wound

by at least 50%," and "screen for prevention of overgrowth" are not indefinite claim limitations. KCI cross-appeals alleging that the district court erred by denying its motion for JMOL of infringement, and alternatively, requests a new trial on infringement because Defendants presented a "practicing the prior art" defense, compared the accused product to KCI's product, and engaged in "class warfare" before the jury.

We have jurisdiction under 28 U.S.C. § 1295(a)(1).

## A. The Asserted Patents

The patents at issue relate to treating difficult-to-heal wounds by applying suction, which is referred to in the patents as "reduced pressure" or "negative pressure." Claims 1 and 11 of the '643 patent, with emphases added, are illustrative:

> 1. An appliance for administering a *reduced pressure treatment to a would* [sic] comprising:
>
> (a) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;
>
> (b) a seal adapted to seal said cover to tissue surrounding the wound;

*Appendix A*

(c) reduced pressure supply means for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath said cover; and

(d) a *screen adapted to prevent overgrowth* of wound tissue, said screen being located between said wound and said cover.

11. A method *treating a wound* comprising the steps of:

(a) applying a reduced pressure to the wound, wherein said applying step comprises the steps of:

(i) placing a porous *screen* over the wound;

(ii) locating an impermeable cover over the wound, said cover having a suction port;

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a *selected stage of healing.*

In addition to claims 1 and 11, KCI asserted claims 2, 3, 6, 7, 8, 12, 13, 14, 16, 26, 27, 28, 29, and 32 of the '643 patent. KCI also asserted claims 1, 3, 5, 8, 9, 11, 12, 13, 27, 31, 33, 36, 37, 54, 56, 58, 61, 62, 64, 65, and 66 of the '081 patent.

The issues on appeal focus on six limitations, at least one of which is present in each of the asserted claims. First, each of the asserted claims in both the '081 and '643 patents requires using "reduced" or "negative" pressure to "treat a wound" or "facilitate the healing of a wound," either as part of the preamble[1] or the body of

1. The parties concede that the preambles are limiting with respect to this limitation.

the claim. Second, there is a "screen" or "screen means" limitation in each asserted claim of the '081 patent and claims 1, 2, 3, 11, and 12 of the '643 patent. Third, claims 12, 27, 33, 36, 37, 65, and 66 of the '081 patent and claims 13, 14, 28, and 29 of the '643 patent have limitations requiring the use of intermittent suction. Fourth, an "impermeable cover" limitation is present in claims 1, 2, 3, 6, 7, 8, 11, 12, 16, 26, 27, and 28 of the '643 patent.[2] Fifth, claims 11, 12, 29, and 32 of the '643 patent contain a limitation requiring treating toward a "selected stage of healing." Finally, claim 32 of the '643 patent recites "a reduction in bacterial density in the wound by at least 50%."

## B. Claim Construction

The parties have devoted significant attention to the construction of "treating a wound" and "facilitating the healing of wounds." Defendants argued before the first claim construction order that "treating a wound," as used in claim 13 of the '643 patent, should be construed as "giving medical care to an injury," or in the alternative, "giving medical care to (1) trauma to any of the tissues in the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical

2. Defendants argue that impermeable covers were well known by persons of ordinary skill in the art. However, as discussed below, KCI presented substantial evidence that the prior art did not teach or suggest the "treating a wound with negative pressure" limitation, which was present in each of the asserted claims. Therefore, it is unnecessary for us to address the "impermeable cover" limitation.

incision." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832, at 5 (W.D. Tex. June 28, 2005) ("*Order Construing Patent '643 Terms*") (alteration in original). In response, KCI argued that "treating a wound" should be construed to mean "treating tissue damage to the surface of the body, including the epithelial and subcutaneous layers," or in the alternative, should not be construed because the jury would have no difficulty understanding the phrase's ordinary meaning. *Id.* at 5-6; Pl.'s Br. on Claim Construction 8-10, *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D.Tex. Mar. 7, 2005). In its first claim construction order, the district court construed the term "according to its plain and ordinary meaning as 'giving medical care to an injury.'" *Order Construing Patent '643 Terms* at 7.

After a *Markman* hearing on November 14, 2005, the district court issued a second claim construction order construing terms from the '643 and '081 patents. *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D.Tex. Jan. 24, 2006) ("*Order Construing Patents '643 and '081 Claim Terms*"). In this order, the court relied on its previous construction of "wound" as "injury" and construed "facilitating the healing of wounds" to mean "facilitating the healing of injuries." *Id.* at 9.

In the middle of the trial, however, the district court suggested vacating the construction of "wound" in light of the fact that the parties had yet to use the word "injury" in front of the jury. After clarifying on the

record that neither party was waiving its right to appeal, the court issued an order vacating its construction of "wound." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D. Tex. June 29, 2006) ("*Second Amended Order Construing Patent '643 and '081 Claim Terms*"). As a result, "treating a wound" was construed to mean "giving medical care to a wound." *Id.* At trial, the jury was given this construction of "treating a wound," but was not instructed on the meaning of "facilitating the healing of wounds."

The construction of the "screen" limitation is also relevant to this appeal. The district court construed this term to mean "a porous material that applies a counteracting force to granulation tissue to stop growth of granulation tissue above the level of skin surrounding the wound, the porous material being positioned at the wound within the sealing means." *Order Construing Patents '643 and '081 Claim Terms* at 16-17.

C. The Prior Art

At trial, Defendants presented several prior art references that are relevant to this appeal. These include the Chariker-Jeter publications, the Chariker-Jeter prior uses, the Svedman article, the Johnson article, and the Davydov publications. KCI distinguished each of these references by arguing to the jury that they did not teach "treating a wound with negative pressure" and thus could not render the claimed invention obvious.

*Appendix A*

The Chariker-Jeter prior art presented at trial included a journal article, a book chapter, testimony from Dr. Chariker about public uses of the Chariker-Jeter system, and assorted presentation materials. The Chariker-Jeter system, as described by these references, was originally developed to treat certain wounds that were complicated by a hole in one of the patient's organs. Such a hole is commonly referred to as a "fistula." In broad terms, the system consists of lining the wound bed with gauze, placing one end of a tube in the wound, sealing a cover over the wound, and applying suction to the other end of the tube. Of the various Chariker-Jeter references, only one prior use, as described by Dr. Chariker in his testimony about the treatment of a patient, specifically disclosed using the Chariker-Jeter system on a wound that did not involve a fistula.

The second piece of prior art relied on by Defendants at trial was the Svedman article. This article describes placing a dressing over a wound, connecting a solution to a tube at one end of the dressing, and applying suction to a tube at the other end of the dressing. The effect is that the solution flows through the dressing and across the surface of the wound.

Defendants' third piece of prior art was the Johnson article, which describes anchoring a skin graft in place, cutting several "pie crust incisions" in the graft, covering the graft with gauze, inserting a suction drain, covering the entire area with a dressing, and applying suction.

The fourth and final piece of prior art was the Davydov reference, which consists of two articles that describe a treatment for infection in the mammary glands of nursing women. The treatment method consists of making an incision in the breast, placing a glass cup over the incision, and applying suction to drain the pus and bacteria.

## II. DISCUSSION

Defendants appeal the district court's denial of their motion for JMOL of obviousness, or in the alternative, their request for a new trial on obviousness. Defendants also appeal the district court's construction of "wound" and its failure to find several claim terms indefinite. KCI cross-appeals the district court's denial of its motion for JMOL of infringement, or, in the alternative, its request for a new trial on infringement. We address each issue in turn.

### A. Defendants' Motion for JMOL of Obviousness

The denial of a motion for JMOL is reviewed "under the law of the regional circuit where the appeal from the district court normally would lie." *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1346 (Fed. Cir. 2007) (quotations omitted). In the Fifth Circuit, JMOL "is appropriate only when a 'reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" *Cambridge Toxicology Group, Inc. v. Exnicios*, 495 F.3d 169, 179 (5th Cir. 2007) (quoting Fed. R. Civ. P. 50(a)(1)). "We must affirm unless there is

no legally sufficient evidentiary basis for the jury's verdict." *Lane v. R.A. Sims, Jr., Inc.*, 241 F.3d 439, 445 (5th Cir. 2001) (internal quotations omitted).

Defendants allege several errors in the district court's treatment of its obviousness contentions. First, Defendants argue that the court's failure to construe "wound" prevented the jury from properly assessing whether the prior art was within the scope of the asserted claims. Second, Defendants argue that the district court erred by finding that substantial evidence supported the jury's finding that the patents were not obvious. Finally, Defendants contend that the district court was required to conduct its own independent obviousness analysis and erred by simply reviewing the jury's verdict for substantial evidence. We address each argument in turn.

1. Construction of "Wound"

Defendants argue that the district court erred by vacating its construction of "wound" when the term's meaning was critical to the obviousness inquiry. According to Defendants, this error allowed KCI to improperly avoid the prior art by arguing claim construction to the jury. Specifically, Defendants take issue with KCI's characterization at trial of the Chariker-Jeter, Svedman, Johnson, and Davydov references as "draining fistulae," "irrigating wounds," "immobilizing skin grafts," and "draining bodily fluids," respectively, as opposed to "treating wounds with negative pressure." Defendants' expert testified that

under the plain and ordinary meaning of "wound," each of the prior art references disclosed "treating a wound with negative pressure." The effect of this, according to Defendants, was that the jury was improperly forced to choose between competing claim constructions offered by the experts.

Defendants ask us to adopt their proposed "plain and ordinary meaning" construction, taken from Stedman's Medical Dictionary: "(1) trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision." They argue that the specification's use of broad language when describing the wounds that can be treated shows that the ordinary meaning, as defined in the dictionary, was intended. *See* '643 patent col.12 ll.41-42 ("Negative pressure appliances are useful for treating a variety of wounds."); *id.* col.13 ll.24-25 ("The present invention also includes a method of treating damaged tissue. . . ."). Additionally, Defendants cite the numerous examples in the '643 patent's specification that describe open wounds, infected wounds, burn wounds, skin graft and skin flap wounds, decubitus ulcer wounds, incisional wounds, chronic open wounds secondary to stasis ulcers, and wounds which respond to increased blood flow, to support their proposed construction.

KCI responds that any error resulting from the district court's failure to construe the "wound" phrases is harmless because Defendants' proposed construction is incorrect as a matter of law and the jury's verdict

demonstrates that it adopted the correct construction. According to KCI, the correct construction of "wound" is "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." KCI argues that while the specification may refer to a "variety of wounds," each and every example specifically described is a skin wound. Therefore, KCI alleges, the Stedman's Medical Dictionary definition is broader than the scope of the specification and cannot be used to define "wound" as used in the claims. Further, KCI notes that under Defendants' proposed construction, "wound" would include, in addition to fistulae, "conditions such as ruptured appendices and stomach ulcers" that the specification in no way suggests can be treated according to the claimed invention. Appellee's Br. 53.

As a threshold matter, it appears that the parties' dispute over the construction of "wound" only affects the Chariker-Jeter and Davydov references. At trial, KCI did not contest that "wounds" were the subject of both the Svedman and Johnson articles. For example, KCI's expert, Dr. Orgill, testified that, in the Johnson reference, "[t]he skin graft is closing the wound." J.A. 204,899. Similarly, Dr. Orgill described the Svedman article as teaching "irrigation of a wound." J.A. 204,923. Therefore, the effect of any error in the failure to construe "wound" is limited to the Chariker-Jeter and Davydov references.[3]

3. Defendants also argue that KCI improperly distinguished the prior art on the ground that it did not "treat" wounds. However, Defendants have not alleged error in the (Cont'd)

We agree with KCI that "wound," as used in the asserted patents, does not cover the fistulae described in the Chariker-Jeter publications and the "pus pockets" described in the Davydov references. As this court held in *Phillips v. AWH Corp.*, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). All of the examples described in the specification involve skin wounds. *See id.* at 1321 ("Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent."). To construe "wound" to include fistulae and "pus pockets" would thus expand the scope of the claims far beyond anything described in the specification. *See Nystrom v. TREX Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005) ("[I]n the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public—i.e., those of ordinary skill in the art-that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply

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district court's construction of "treating" as "giving medical care to," nor have they asked us for a construction of "facilitating the healing of." *See Second Amended Order Construing Patent '643 and '081 Claim Term* at 2. Therefore, we confine our inquiry to the construction of "wound."

because it may be found in a dictionary, treatise, or other extrinsic source.").

We further conclude that the district court's failure to instruct the jury on the construction of "wound" in this case was harmless.[4] *See B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1423 (Fed. Cir. 1997) (holding that the district court's pre-*Markman* failure to instruct the jury on the construction of a means-plus-function limitation was harmless because the jury adopted the correct construction). Because the jury's verdict is supported under the proper construction, and because we perceive no danger under the circumstances of this case that the jury may have used an incorrect construction of "wound" that might have prejudiced Defendants, there is no need to remand for a new trial.

2. Substantial Evidence of Nonobviousness

Defendants next argue that regardless of which claim construction is used, the prior art references disclose "treating wounds with negative pressure."

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4. While *O2 Micro International, Ltd. v. Beyond Innovation Technology Co.*, 521 F.3d 1351 (Fed. Cir. 2008), permits a remand for further claim construction, it does not require one. Remanding is particularly unnecessary in this case, where claim construction was briefed before the district court and the disputed term was initially construed but later vacated because the parties did not use the construction in front of the jury. *See id.* at 1363 (remanding because "the district court is in the best position to determine the proper construction of this claim term in the first instance").

In support of this, Defendants cite the Chariker-Jeter publications that describe treatment of wounds complicated by fistulae, Dr. Chariker's testimony about the use of that method on a wound that did not include a fistula, the Svedman article, the Johnson article, and the Davydov articles.

The scope and content of the prior art are factual questions to be determined by the jury. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966). This court reviews these factual determinations, "whether explicit or implicit within the verdict, for substantial evidence." *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001).

Defendants primarily rely on the Chariker-Jeter references, including the publications and Dr. Chariker's testimony at trial. However, KCI distinguished these references in front of the jury and presented substantial evidence that these references did not disclose "treating wounds with negative pressure." For example, Dr. Argenta, a witness for KCI and one of the named inventors on the asserted patents, testified that the Chariker-Jeter system is "totally different" from the claimed invention. Specifically, Dr. Argenta stated that the Chariker-Jeter method was designed for draining the effluent from fistulae, not treating a wound in order to increase granulation. Additionally, KCI's expert, Dr. Orgill, testified that the Chariker-Jeter references "deal[ ] with draining fistulas only, no[t] healing of the wound." With respect to Dr. Chariker's testimony about the use of the method on a patient whose wound did not

include a fistula, KCI purports to have impeached Dr. Chariker's testimony about this patient with contradictory deposition testimony. The jury was correctly instructed, however, that it was the "sole judge[ ] of credibility" and that it must decide which witnesses to believe. Moreover, Fifth Circuit law dictates that "in case[s] of conflicting expert testimony, the jury is entitled to make credibility determinations and believe the witness it considers more trustworthy." *Streber v. Hunter*, 221 F.3d 701, 726 (5th Cir. 2000) (quotations omitted). Based on our review of the record, we find that the testimony of KCI's witnesses was sufficient to allow the jury to reach the conclusion that the Chariker-Jeter method was not used to "treat a wound with negative pressure" as required by the claims.

We reach the same conclusion regarding the Svedman, Johnson, and Davydov articles. Dr. Orgill distinguished the Svedman technique on two grounds. First, Dr. Orgill told the jury that Svedman taught an irrigation device, not a device for treating a wound with negative pressure. Second, Dr. Orgill explained that the Svedman technique could not maintain negative pressure on the wound because the Vaseline between the dressing and the wound would become viscous when warmed by contact with human skin. With respect to the Johnson article, Dr. Orgill told the jury that the skin graft, not the negative pressure, was treating the wound. According to Dr. Orgill, the Johnson article simply described one of many ways to immobilize a skin graft to a wound. Finally, Dr. Orgill testified that Davydov did not teach treatment of a "wound" with

negative pressure. Rather, Dr. Orgill explained, the Davydov method was used to treat a "pocket of pus" that was "enclosed within the breast." According to Dr. Orgill, the only wound disclosed in the Davydov articles was the incision made to gain access to the "pocket of pus," which did not begin to heal until the suction device was removed.

Thus, KCI addressed each of Defendants' prior art references and provided the jury with a basis for determining that they did not teach or suggest "treating a wound with negative pressure," a limitation found in every asserted claim. We conclude that this was sufficient to support the jury's verdict of nonobviousness.[5]

### 3. The District Court's Review of the Jury's Verdict on Obviousness

Defendants' final argument with respect to its JMOL motion is that the district court erred by failing to conduct its own obviousness analysis. Defendants do not argue that submitting the question of obviousness to the jury is error. However, they assert that the district court strayed by "treat[ing] the obviousness conclusion as a pure factual question" and simply reviewing the jury's verdict for substantial evidence.

5. While this appeal was pending, claim 13 of the '643 patent was rejected during reexamination as obvious in view of two other Svedman references that were not relied on by Defendants in this appeal. Because those references were not argued before us, the results of the reexamination have no effect on this appeal.

Appellant's Br. 54. Because of this, Defendants argue, the district court never considered which *Graham* factors justified a nonobviousness verdict. Defendants allege that had such an analysis occurred, the district court would have concluded that the asserted patents were obvious.

Defendants' obviousness argument at trial relied heavily on the prior art references, the scope and content of which are factual questions to be determined by the jury. *See Graham*, 383 U.S. at 17. As discussed above, KCI presented substantial evidence to support its interpretation of the references. Thus, we must assume that the jury found that the prior art does not disclose "treating a wound with negative pressure" within the meaning of the patents. *See Arsement v. Spinnaker Exploration Co.*, 400 F.3d 238, 249 (5th Cir. 2005) (on appeal of a motion for JMOL, "the evidence, as well as all reasonable inferences from it, are viewed in the light most favorable to the verdict" (quotations omitted)). In light of this, we conclude that Defendants failed to establish that the asserted claims were obvious as a matter of law.

### B. Defendants' Request for a New Trial on Obviousness

In the alternative to their request for JMOL of obviousness, Defendants seek a new trial on obviousness because of alleged errors in the jury instructions. At trial, the jury was instructed that:

> In order to prove obviousness, [Defendants] *must* prove by clear and convincing evidence that one of ordinary skill in the art at the time would have found in the prior art some teaching, suggestion or incentive to combine the prior art in the way [KCI] did in its invention.

J.A. 235 (emphasis added). Defendants concede that they stipulated to this instruction, but argue that a supervening change in the law resulting from *KSR* justifies their raising this issue for the first time on appeal. KCI responds that because Defendants stipulated to the instruction, any error was "invited" and is thus unreviewable. For the purpose of this review, we assume arguendo that Defendants did not invite the alleged error in the jury instructions.

Challenges to jury instructions are reviewed "under the law of the regional circuit where the district court sits." *Voda v. Cordis Corp.*, 536 F.3d 1311, 1328 (Fed. Cir. 2008). In the Fifth Circuit, an objection to the jury instructions first raised on appeal must "meet the exacting requirements of plain error." *Tompkins v. Cyr*, 202 F.3d 770, 784 (5th Cir. 2000). "To overturn a verdict for plain error in the instructions, we must find an obviously incorrect statement of law that was probably responsible for an incorrect verdict, leading to substantial injustice." *Id.* (citations and quotations omitted).

As discussed above, substantial evidence supports a finding that the Chariker-Jeter, Svedman, Johnson, and Davydov prior art references do not "treat wounds with negative pressure" as claimed in the asserted patents. The alleged error in the jury instruction relates to the "teaching, suggestion, or incentive to combine the prior art." Based on our conclusion that there was substantial evidence that *none* of the prior art references "treat wounds with negative pressure," we are not persuaded that the instruction on obviousness was "probably responsible for an incorrect verdict." *See id.*; *see also z4 Techs.*, 507 F.3d at 1355 (affirming denial of a new trial on obviousness after *KSR* because defendants failed to identify evidence establishing a prima facie case of obviousness). Accordingly, we affirm the district court's denial of Defendants' request for a new trial.

### C. Defendants' Indefiniteness Arguments

The definiteness analysis requires a determination of "whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998) (quoting *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993)). "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Res. & Eng'g Co. v. United States*, 265 F.3d 1371,

1375 (Fed. Cir. 2001). Definiteness is a question of law, which we review de novo. *Id.* at 1376.

Defendants first argue that "selected stage of healing" is indefinite because the specification does not explain how the selected stage is to be determined for particular wounds at particular times. Further, Defendants argue that whether a wound has progressed to a selected stage of healing is wholly subjective. However, KCI points out that the specification of the '643 patent provides several examples of selected stages of healing. '643 patent col.12 ll.47-54. Additionally, KCI submitted a declaration from one of the named inventors of the asserted patents explaining that a doctor of ordinary skill in the art would understand how the selected stage of healing may vary from wound to wound. While it may be true that the patentee's ability to "articulate a definition supported by the specification . . . does not end the inquiry," Defendants have not shown in this case that a person of skill in the art would be unable to ascertain the meaning of the term. *See Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008). Accordingly, we conclude that "selected stage of healing" is not "insolubly ambiguous." *See Exxon*, 265 F.3d at 1375.

Relying on *Honeywell International, Inc. v. International Trade Commission*, 341 F.3d 1332, 1339-40 (Fed. Cir. 2003), Defendants also argue that "reduction in bacterial density in the wound by at least 50%" is indefinite because there are several methods for measuring bacterial density, each of which may yield

a drastically different result, and a person of ordinary skill in the art would not know which method to use. However, KCI responds that a person of ordinary skill in the art would know which method to use because Example 2 of the '643 patent describes a particular method. '643 patent col.15 ll.58-65. We agree with KCI that *Honeywell* does not control where, as here, several methods for calculating reduction in bacterial density are available but the specification discloses one particular method. Thus, we conclude that "reduction in bacterial density in the wound by at least 50%" is not indefinite.

Finally, Defendants argue that the claims reciting a "screen" are indefinite because a person of skill in the art would not know what "overgrowth of tissue in the wound" is or how a "screen" could prevent it. Defendants point to several parts of the record that allegedly present conflicting definitions of "preventing overgrowth," such as "preventing loculation," "removing bacteria," "removing dead tissue that sticks to the screen," and "preventing the formation of scar tissue." KCI argues in response that one of the named inventors defined overgrowth as "[g]rowth of granulation tissue above the surrounding uninjured tissue" and explained that the screen prevented this by "distribut[ing] the pressure" within the wound. KCI also asserts that the allegedly conflicting definitions are not definitions of "overgrowth" at all. Instead, KCI argues, Defendants are pulling quotes from the inventors' deposition testimony about various complications of wound healing and attempting to mischaracterize them

as definitions of "overgrowth." In light of KCI's explanation of the record before us, we are not persuaded that this claim term is "insolubly ambiguous." *See Exxon*, 265 F.3d at 1375. Accordingly, we find no error in the district court's failure to find the term indefinite.

### D. KCI's Motion for JMOL of Infringement

We turn now to KCI's cross appeal on infringement. While several infringement theories were presented at trial, KCI limits its cross appeal to Blue Sky Medical Group, Inc.'s ("Blue Sky") alleged direct and induced infringement resulting from its sale of Versatile kits. Blue Sky assembles and sells several Versatile kits, each of which includes a Versatile pump and a combination of various "convenience items." The most basic kits include a Versatile pump, tubing, and a drain. Other kits include items such as Aquaphor gauze, adhesive dressing, scissors, and gloves. KCI alleges that Blue Sky's sale of certain kits directly infringed the asserted apparatus claims of the '081 patent and induced infringement of both the '081 claims and several method claims of the '643 patent. The jury rejected these contentions and the district court denied KCI's motion for JMOL.

#### 1. Direct Infringement

KCI first argues that the undisputed evidence proved that two of Blue Sky's Versatile kits, "Chariker-Jeter Plus" and "Complete," directly infringed each of the twenty-one asserted claims of the '081 patent.

According to KCI, the only disputed limitation in these claims was the requirement of a screen for preventing overgrowth of tissue in the wound. KCI alleges that it was undisputed that the Aquaphor contained in both kits satisfied this limitation. KCI relies primarily on the testimony of its expert, Dr. Orgill, who argued that Aquaphor "looks like a screen," "has the semi-rigid properties described in the patent," and is used "to restrain overgrowth of granulation tissue and help provide even distribution of the suction." According to KCI, a reasonable jury could not have found for Blue Sky because Blue Sky never presented any evidence that Aquaphor does not prevent overgrowth.

Blue Sky responds with two grounds on which we could affirm the district court's denial of KCI's motion for JMOL. First, it argues that KCI accused eighteen products, six of which did not contain Aquaphor or anything else alleged to have satisfied the screen limitations, but then stipulated to a verdict form that did not differentiate between the various kits. Blue Sky contends that KCI thus treated infringement as an "all or nothing matter" and cannot now complain about the lack of specificity in the verdict. We need not decide the viability of this "all or nothing" theory, which is contested by KCI, because Blue Sky's second argument, that there was indeed a dispute over whether Aquaphor served to prevent overgrowth, is determinative.

Blue Sky cites the testimony of co-founder Tim Johnson, who explained to the jury that Aquaphor is a "soft, flexible, conforming gauze." Blue Sky also points

out that the jury observed Aquaphor gauze and had the opportunity to assess its rigidity. Additionally, Blue Sky cites testimony that the purpose of the Aquaphor was to prevent granulation tissue from attaching to either the foam screen or fluffed gauze that was placed in the wound, which allowed the jury to infer that Aquaphor did not prevent overgrowth. Finally, Blue Sky asserts that the jury was not required to accept Dr. Orgill's "wholly conclusory" testimony.

We decline to require the jury to accept the testimony of KCI's lone infringement witness, Dr. Orgill. The jury was instructed that it was not required to accept any particular witness's testimony, and the Fifth Circuit has made clear that the jury is entitled to disbelieve a party's expert if it chooses. *See Streber*, 221 F.3d at 726. Additionally, while Defendants' evidence may not have been overwhelming, it was nonetheless sufficient to support the jury's conclusion that KCI failed to meet its burden of proving that the Aquaphor prevented overgrowth.

2. Induced Infringement

KCI also appeals the denial of its motion for JMOL that Blue Sky induced infringement of claims 13, 14, and 29 of the '643 patent, each of which is a method claim that recites the use of intermittent suction. Importantly, none of these claims require a screen for the prevention of overgrowth. KCI points out that the Versatile manual explains that it "is designed for operation in two suction modes—*continuous* and *intermittent*." Additionally,

KCI alleges, Blue Sky told customers that "pressure can be altered . . . to an intermittent setting" and gave express instructions to "[s]elect continuous or intermittent suction mode." KCI cites testimony from a Blue Sky witness that "[m]any of our patients have pain with the intermittent use" as further proof that customers actually followed these instructions. Finally, at trial, KCI presented a statement from one of Blue Sky's distributors that Blue Sky told it that intermittent pressure was "[s]ometimes successful."

Blue Sky does not dispute that the Versatile is capable of using intermittent suction. Instead, Blue Sky argues that the jury's verdict is correct because KCI failed to prove both actual direct infringement and that Blue Sky had the requisite intent for inducement. With respect to direct infringement, Blue Sky argues that when the testimony KCI relies on—"many of our patients have pain with intermittent use"—is read in context, it is unclear whether the witness, a nurse with thirty years of experience using negative pressure wound therapy, was referring to use of the Versatile or use of KCI's commercial embodiment, the VAC. According to Blue Sky, such ambiguous testimony cannot support, let alone require, an inference of direct infringement. Blue Sky also argues that the product manuals and other circumstantial evidence, without more, are insufficient to prove infringement as a matter of law under *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986). Finally, Blue Sky argues that testimony from its principals, Tim Johnson and Richard Weston, provided substantial evidence to

support the jury's finding that Blue Sky lacked the level of intent necessary for inducement.

To prove induced infringement, the plaintiff must prove both direct infringement and "that the defendant possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). We conclude that substantial evidence supports a finding that Blue Sky lacked the necessary intent. Tim Johnson testified that Blue Sky never intended to infringe KCI's patents. Richard Weston testified that he thought that because the Versatile simply performed the Chariker-Jeter method, which was in the public domain, KCI's patents could pose no barrier to Blue Sky entering the market. KCI may be correct that "practicing the prior art" is not a defense to patent infringement. *See Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1377 (Fed. Cir. 2002). However, it does not follow that a defendant's belief that it can freely practice inventions found in the public domain cannot support a jury's finding that the intent required for induced infringement was lacking. The jury heard Blue Sky's founders explain why they did not believe they were infringing and had the opportunity to assess their credibility. We find no basis to overturn the jury's decision with respect to inducement.

*Appendix A*

E. KCI's Motion for a New Trial

In the alternative to its motion for JMOL, KCI requests a new trial on infringement. In the Fifth Circuit, the district court's denial of a motion for a new trial is reviewed for abuse of discretion. *Industrias Magromer Cueros y Pieles S.A. v. La. Bayou Furs Inc.*, 293 F.3d 912, 924 (5th Cir. 2002).

KCI alleges that Defendants' "practicing the prior art" defense, comparisons of the Versatile to the VAC, and "blatant class-warfare arguments," including references to KCI's wealth and the need for an inexpensive alternative to the VAC, prejudiced the jury and resulted in an incorrect verdict.

Blue Sky responds that any comparisons between the Versatile and the Chariker-Jeter prior art references were relevant to rebut KCI's allegations of copying and willful infringement, to prove lack of intent to induce infringement, and to impeach KCI's expert's unsubstantiated distinctions between the gauze in the prior art and the gauze used with the Versatile. Similarly, Blue Sky asserts that the comparisons between the VAC and the Versatile were relevant in response to KCI's allegations that Blue Sky blatantly copied the VAC. Finally, Blue Sky argues that its references to KCI's wealth were relevant to prove the bias of KCI's witnesses and respond to KCI's arguments that Blue Sky was more interested in profits than patients.

We agree with Defendants and the district court that the arguments to which KCI objects had proper uses or were made in response to issues raised by KCI. The district court expressly found that Defendants' arguments did not amount to class warfare. Additionally, the jury was specifically instructed that it should not treat anyone unfairly based on wealth. Accordingly, we find no abuse of discretion in the court's denial of KCI's motion for a new trial.

## III. CONCLUSION

For the foregoing reasons, we affirm the district court's denial of Defendants' motion for JMOL of obviousness and its determinations that certain claim terms were not indefinite. We also deny Defendants' request for a new trial on obviousness. With respect to KCI's cross-appeal, we affirm the district court's denial of KCI's motion for JMOL of infringement and its request for a new trial on infringement.

*AFFIRMED.*

*Appendix A*

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

2007-1340, -1341, -1342

KINETIC CONCEPTS, INC., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences,

Plaintiffs-Cross Appellants,

v.

BLUE SKY MEDICAL GROUP, INC.,

Defendant-Appellant,

and

RICHARD S. WESTON,

Defendant-Appellant,

and

MEDELA AG and MEDELA, INC.,

Defendants-Appellants.

Appeals from the United States District Court for the Western District of Texas in case no. 03-CV-0832, Judge W. Royal Furgeson, Jr.

*Appendix A*

DYK, *Circuit Judge*, dissenting.

I respectfully dissent from the majority's holding that affirms the judgment that the claims are nonobvious. In my view, the majority improperly holds that the claim term "wound" can be limited to the disclosed embodiments in the specification, and, having done so, then misreads the specification as showing only embodiments treating harm to the surface of the body or skin wounds. Under the correct construction of this claim term, the asserted claims of U.S. Patent Nos. 5,636,643 ("'643 Patent") and 5,645,081 ("'081 Patent") would have been obvious.[1]

I

The proper construction of the term "wound" was extensively disputed pre-trial. Defendants Medela AG and Medela, Inc. ("Defendants") argued that "wound" should be construed according to its plain meaning as "injury." Defendants alternatively argued that "wound" should be construed as found in *Stedman's Medical Dictionary* (26th ed.): "(1) trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision."

Plaintiffs Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health

1. The asserted claims are claims 1-3, 6-8, 11-14, 16, 26-29, and 32 of the '643 patent, and claims 1, 3, 5, 8, 9, 11-13, 27, 31, 33, 36, 37, 54, 56, 58, 61, 62, and 64-66 of the '081 patent.

Sciences ("Plaintiffs") argued that "treating a wound" should not be construed at all because it is well within the common experience and understanding of every juror. Plaintiffs argued in the alternative that "wound" should be construed as "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." Although both parties introduced expert reports on claim construction to the district court, neither party relies on these expert reports on appeal.

Initially, the district court construed "wound" as "injury." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832, at 5 (W.D. Tex. June 28, 2005) ("Order *Construing Patent '643 Terms*"). However, after approximately ten days of trial, the district court decided *sua sponte* that it would adopt the Plaintiffs' approach and not instruct the jury on the proper construction of "wound." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D. Tex. June 29, 2006) ("*Second Amended Order Construing Patent '643 and '081 Claim Terms*").

At trial, Plaintiffs argued the definition of "wound" to the jury in an effort to distinguish the prior art, particularly the public uses of Chariker and Jeter that involved applying negative pressure to surgical incisions including both a hole in the skin and a "fistula" or hole in an internal organ. Plaintiffs argued to the jury that a "fistula" was distinct from a "wound," and that the

purpose of the public uses of Chariker and Jeter was "fistula drainage" as opposed to "wound healing."[2]

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2. In opening and closing arguments, Plaintiffs attempted to distinguish the public uses of Chariker and Jeter by focusing on the fact that the method was usually used when there was a fistula: "this [Chariker-Jeter] is about fistulas, not about the wounds that we are talking about," J.A. 200862; "Remember Chariker-Jeter is healing—is drainage, not healing. Chariker-Jeter is fistula only," J.A. 205656; "Now, let's talk about Chariker-Jeter and I will repeat myself 400 times and I will shut up. Chariker-Jeter, fistulas, fistulas, fistulas, fistulas. It's about drainage," J.A. 205665. The testimony of Plaintiffs' expert witness on validity, Dr. Orgill, is also illustrative:

> Q: Is that wound healing?
>
> A: No. That's fistula drainage.
>
> Q: And why isn't that wound healing?
>
> A: Well, Chariker-Jeter describes that they stop this device when the fistula closes. And usually these devices take about 16 days, that's what they describe in their article, for this nasty fluid to stop coming out. And after that, when the fistula closes, then that's when the wound healing or the rest of the wound can start to heal.

J.A. 204932-35. Cross-examination on the definition of wound included an answer from this witness that "[v]ery often people with the definition of tissue would separate tissues from organs, so, in other words, many people in their definition of tissue

(Cont'd)

II

The district court's failure to construe the term "wound" was a clear error. We have held that "[w]hen the parties raise an actual dispute regarding the proper scope of [the patent] claims, the court, not the jury, must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). It is improper to argue claim construction to the jury because the "risk of confusing the jury is high when experts opine on claim construction." *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172-73 (Fed.Cir. 2005); *see Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364 n. 6 (Fed. Cir. 2008). In this case, the definition of the term "wound" was central to the case and a primary focal point of the *Markman* hearing; as a result, the court should have construed the term "wound."

The appellees do not dispute that it was error to fail to construe wound, instead claiming that the issue "need not be resolved, however, since any error was harmless" under the claim construction now adopted by the majority. Appellee's Br. 51. The majority agrees.

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(Cont'd)

might not consider, for example, a kidney to be a tissue. I understand some people would, but some people would separate organ from tissues." J.A. 205092. Testimony by an inventor also focused on this distinction: "It's totally different. They're treating drainage. We're treating a wound. . . . We're treating to close a wound. They're treating to control the fistula."

However, there is no suggestion by either the majority or the appellees that the verdict could be sustained under the appellants' proposed construction. Thus, the crucial question is whether the majority's claim construction is correct. In my opinion it is not.

III

The majority construes "wound" to mean "tissue damage to the surface of the body, including the epithelial and subcutaneous layers" because "[a]ll of the examples described in the specification involve skin wounds." Maj. op. at 1019. It is the words of the claim that define the scope of the patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The words are generally construed according to their ordinary and customary meaning, that is, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. This meaning is to be interpreted in the context of the entire patent, including the specification. *Id.* However, it is improper to import limitations from the specification into the claims where there is no indication that the specific examples in the specification are intended to be strictly coextensive with the claim. *Id.* at 1323.

The majority holds that the term "wound" should be understood as limited to damage to tissues near the surface of the body, particularly the skin, and should not include damage to organs. The majority points to no medical dictionary or other extrinsic evidence

supporting this claim construction. The specification does not define "wound" or provide any examples of the types of harms that would *not* qualify as wounds under the claim terms. Nor does the specification state that the examples listed in the specification were intended to describe the entire invention. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001) (specification described "all embodiments of the present invention"). Nonetheless, the majority concludes that, because the specification examples supposedly only include descriptions of damage to the skin, the specification limits the kinds of wounds encompassed by the claim. In my view, our decision in *Phillips* bars us from construing the claims as limited by the specification examples, and the majority's approach is without support in our post-*Phillips* cases.

But even if the examples could limit the claims, in my view the examples here are not limiting, and indeed the specifications confirm the inappropriateness of the majority's construction. The specifications of both patents make clear that the examples are merely "illustrative."[3] The specifications also state that the

3. The '081 Patent specification states: "[t]hese examples are provided for illustrative purposes only and are not to be taken as limiting," col.5 ll.47-49, and "[t]he foregoing examples are illustrative of the present invention, and are not to be construed as limiting thereof," col.9 ll.46-48. *See also* '643 Patent col.21 ll.43-45 ("The terms and expressions which have been employed are used as terms of description and not of limitation.").

invention is "useful for treating a variety of wounds." '643 Patent col.12 ll.41-42. "Wounds that have exhibited positive response to treatment by the application of negative pressure *include* infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached." '643 Patent col.2 ll.58-62. (emphasis added). The use of the illustrative and open language of "include" demonstrates that there may be other types of wounds that the specification does not expressly point out, but that would nonetheless be covered by the claim term "wound." *See SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1284 (Fed. Cir. 2005); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1344-45 (Fed. Cir. 2003). Throughout the specifications, the term "wound" is used only in this broad and inclusive way. *See, e.g.*, '643 Patent col. 13 ll.23-29.

Moreover, the majority is incorrect in asserting that "[a]ll of the examples described in the specification involve skin wounds." Maj. op. at 1019. In fact, a number of examples illustrate that the wounds at issue are not merely skin wounds but deep wounds that include damage to more than the skin, such as wounds in which bone was exposed, '643 Patent col.19 ll.35-39, col.20 ll.23-27, large quantities of fluid were draining, '643 Patent col.19 ll.23-26, surgical incisions cut through the abdominal wall and did not heal, '643 Patent col.19 ll.55-65, or bone was infected, '643 Patent col.20 ll.49-61. *See also* '081 Patent col.8 ll.58-67, col. 9 ll.19-27, ll.35-41. These examples disclose wounds with far more than mere "damage to the epithelial and subcutaneous

layers," suggesting that other kinds of damage, including fistulae caused by surgical incision, would be within the definition of "wound" as used in the claim. These examples explicitly identify benefits achieved in the healing of interior tissue. For example, '643 Patent col.19 ll.55-65 and '081 Patent col.8 ll.60-65 describe increased healing of the abdominal wall by granulation tissue in and through Prolene mesh, and '643 Patent col.19 ll.23-26 and '643 Patent col.20 ll.25-35 describe draining fluid from interior infections.[4]

In view of the inclusive language and examples of the specification, I would find a dictionary frequently used by a person of ordinary skill in the art significant in understanding the meaning of "wound" in the claim. *See Phillips*, 415 F.3d at 1322-23 ("[J]udges are free to consult dictionaries and technical treatises . . . when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d

4. To be sure, one of the identified purposes of the invention applies only to the skin. *See* '643 Patent col.1 ll.20-25 (describing the "zone of stasis" in which blood flow to the skin around a wound is restricted as a problem addressed by the invention). However, we have held that "[t]he court's task is not to limit claim language to exclude particular devices because they do not serve a perceived 'purpose' of the invention. . . . An invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that invention be limited to encompass all of them." *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1370 (Fed. Cir. 2003).

1576, 1584 n. 6 (Fed. Cir. 1996))). The definition of "wound" provided by *Stedman's*, an accepted medical dictionary,[5] includes "trauma to any of the tissues of the body" and "surgical incision." In light of the disclosures of the specifications and the additional support of the dictionary, in my view the term "wound" as used in the claim includes fistulae caused by surgical incision.

IV

The uncontroverted evidence demonstrates obviousness under the construction that I would adopt. Extensive evidence was presented at trial of public uses to heal fistula's caused by surgical incisions, by both Dr. Chariker and Dr. Jeter.[6] There was no testimony to the contrary, nor is there any contention that the claims would be nonobvious if "wound" were construed as I suggest. Under the correct claim construction the undisputed evidence demonstrates that the claims would have been obvious.

For the foregoing reasons, I respectfully dissent.

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5. Plaintiffs' expert witness testified that *Stedman's* is a medical dictionary used in the profession. Plaintiffs even referenced the definition of wound provided by *Stedman's* in filings to the FDA describing the full scope of wounds that could be treated by their device.

6. The parties do not dispute that this evidence meets the definition of a prior art public use under 35 U.S.C. § 102(b).

## APPENDIX B — VERDICT

Question 17

### OBVIOUSNESS OF THE '643 PATENT

Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '643 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 17, please refer to pages 25-34 and 38-45 of the Court's Instructions.

Please answer "Yes" or "No" in each of the blanks below:

| | | | |
|---|---|---|---|
| Claim 1 | No | Claim 13 | No |
| Claim 2 | No | Claim 14 | No |
| Claim 3 | No | Claim 16 | No |
| Claim 6 | No | Claim 26 | No |
| Claim 7 | No | Claim 27 | No |
| Claim 8 | No | Claim 28 | No |
| Claim 11 | No | Claim 29 | No |
| Claim 12 | No | Claim 32 | No |

Please proceed to the next question.

*Appendix B*

## OBVIOUSNESS OF THE '081 PATENT

Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '081 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 18, please refer to pages 25-34 and 38-45 of the Court's Instructions.

Please answer "Yes" or "No" in each of the blanks below:

| | | | |
|---|---|---|---|
| Claim 1 | No | Claim 36 | No |
| Claim 3 | No | Claim 37 | No |
| Claim 5 | No | Claim 54 | No |
| Claim 8 | No | Claim 56 | No |
| Claim 9 | No | Claim 58 | No |
| Claim 11 | No | Claim 61 | No |
| Claim 12 | No | Claim 62 | No |
| Claim 13 | No | Claim 64 | No |
| Claim 27 | No | Claim 65 | No |
| Claim 31 | No | Claim 66 | No |
| Claim 33 | No | | |

Please proceed to the next question.

## APPENDIX C — FINAL JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS, SAN ANTONIO DIVISION FILED AUGUST 29, 2006

**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF TEXAS**
**SAN ANTONIO DIVISION**

No. SA-03-CA-0832 – RF

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC. and WAKE FOREST UNIVERSITY HEALTH SCIENCES

Plaintiffs,

v.

BLUESKY MEDICAL CORPORATION, MEDELA AG, MEDELA, INC., and PATIENT CARE SYSTEMS, INC.

Defendants.

### FINAL JUDGMENT

On June 1, 2006, the court called this case for trial before a duly impaneled and sworn jury. Plaintiffs Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences ("Plaintiffs") appeared in person through their corporate representatives and counsel of record. Defendants

*Appendix C*

BlueSky Medical Corporation, Medela AG, and Medela, Inc. appeared in person through their corporate representatives and counsel of record. Defendant Richard Weston appeared personally and through his counsel of record. Defendants BlueSky Medical Corporation, Richard Weston, Medela AG, and Medela, Inc. are referred to collectively herein as "Defendants."

Prior to trial, the Court ruled on certain claims brought by the parties. Those rulings are incorporated into this Final Judgment. Interrogatories were submitted to the jury by the Court on the remaining claims. The jury answered those interrogatories.

The Court, having considered the verdict and all things both to the law and the evidence, now enters judgment in this case. It is hereby ORDERED, ADJUDGED, AND DECREED that:

1. The Plaintiffs take nothing on their claims against Defendants; and

2. Medela, Inc. and Medela AG take nothing on their counterclaims against the Plaintiffs for declarations of patent invalidity and patent unenforceability

It is so ORDERED.

Signed this 29th day of August, 2006.

s/ Royal Furgeson
ROYAL FURGESON
UNITED STATES DISTRICT JUDGE

## APPENDIX D — ORDER DENYING DEFENDANT MEDELA'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR, ALTERNATIVELY, A NEW TRIAL ON PATENT INVALIDITY AND DEFENDANT BLUESKY'S MOTION FOR NEW TRIAL OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS, SAN ANTONIO DIVISION FILED APRIL 4, 2007

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

No. SA-03-CV-832-WRF

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., AND WAKE FOREST UNIVERSITY HEALTH SCIENCES,

*Plaintiffs*,

v.

BLUESKY MEDICAL CORPORATION, MEDELA AG, MEDELA, INC., AND PATIENT CARE SYSTEMS, INC.,

*Defendants*.

*Appendix D*

## ORDER DENYING DEFENDANT MEDELA'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR, ALTERNATIVELY, A NEW TRIAL ON PATENT INVALIDITY AND DEFENDANT BLUESKY'S MOTION FOR NEW TRIAL

BEFORE THE COURT is Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity (Docket No. 791), filed September 13, 2006 and Plaintiffs' Response (Docket No. 816), filed under seal October 23, 2006. After due consideration of the parties' briefing, the facts, and the applicable law, the Court is of the opinion that Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity should be DENIED. To the extent that Defendant BlueSky's Motion for New Trial (Docket No. 797) seeks the same relief as Medela, BlueSky's Motion is similarly DENIED.

### FACTUAL AND PROCEDURAL BACKGROUND

Defendants Medela AG and Medela, Inc. (collectively "Medela") filed this Motion for Judgment as a Matter of Law or New Trial following a six-week long jury trial concerning patent invalidity, unenforceability, and infringement. At the end of trial, the jury concluded that Plaintiffs take nothing on their patent infringement claims and Defendant Medela take nothing on its counterclaims of patent invalidity and patent unenforceability. Due to the length of both the

trial and the transcript in this case, the Court is well aware of the pertinent facts, which will not be reiterated here.

## STANDARD OF REVIEW

### A. Standard of Review for Judgment as a Matter of Law

"A motion for judgment as a matter of law . . . in an action tried by jury is a challenge to the legal sufficiency of the evidence supporting the jury's verdict."[1] A court must consider all the evidence before the jury and draw all reasonable inferences in favor of the nonmovant, and cannot weigh the evidence or make credibility determinations.[2] A court should enter judgment as a matter of law when "the facts and references point so strongly and overwhelmingly in the movant's favor that reasonable jurors could not reach a contrary conclusion."[3]

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1. *Flowers v. S. Reg'l Physician Servs.*, 247 F.3d 229, 235 (5th Cir. 2001) (internal quotations omitted) (quoting *Ford v. Cimarron Ins. Co., Inc.*, 230 F.3d 828, 830 (5th Cir. 2000)).

2. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150-51 (2000).

3. *Coffel v. Stryker Corp.*, 284 F.3d 625, 630 (5th Cir. 2002).

## B. Standard of Review for a New Trial

Trial judges may grant new trials "for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States."[4] This broad authority includes granting a new trial if "the verdict is against the great-not merely the greater-weight of the evidence."[5] The "great weight of the evidence" standard is not easily met, but a verdict can be against the "great weight of the evidence," and thus justify a new trial, even if there is substantial evidence to support it.[6] In ruling on a motion for new trial, the trial court may weigh the evidence. To grant a motion for new trial, however, the trial judge "must be convinced that the verdict is against the great weight of the evidence."[7]

## DISCUSSION

Because a patent is presumed valid, the quantum of proof required at trial to find invalidity is clear and

---

4. FED. RULE CIV. P. 59(a).

5. *Conway v. Chem. Leaman Tank Lines, Inc.*, 610 F.2d 360, 362 (5th Cir. 1980) (per curiam) (citing *Spurlin v. Gen. Motors Corp.*, 528 F.2d 612, 620 (5th Cir. 1976)).

6. *Shows v. Jamison Bedding, Inc.*, 671 F.2d 927, 930-31 (5th Cir. 1982).

7. *Id.*

convincing evidence.[8] Thus, to grant judgment as a matter of law, Defendant Medela must meet the difficult burden of proving that no reasonable jury could have decided that Medela failed to meet its clear and convincing burden. To grant a new trial, Medela must show that the great weight of evidence clearly and convincingly proved invalidity.

Attempting to meet this difficult burden, Medela argues both in its original motion and in its supporting reply, that the jury's findings are contrary to the great weight of the evidence in three areas: (1) Medela proved by clear and convincing evidence that prior public uses, public knowledge, and sales of the claimed negative pressure systems and devices invalidated the asserted claims of the patents-in-suit; (2) Medela proved by clear and convincing evidence that prior art anticipated or made obvious each of the asserted claims of the patents-in-suit; and (3) if the Court does not grant judgment as a matter of law that the asserted claims are invalid, Medela seeks a new trial on patent invalidity that would include the testimony of David Tumey and Marie McGregor. The Court explains each of these assertions and Plaintiffs' responses, in turn.

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8. 35 U.S.C. § 282 (2002) ("A patent shall be presumed valid."); *Sid W. Richardson, Inc. v. Bryan*, 144 F. Supp. 916, 919 (S.D. Tex. 1956), *affirmed*, 254 F.2d 191, *cert. denied*, 358 U.S. 815.

*Appendix D*

## A. Defendant Medela's Arguments

### *1. Prior public use, knowledge, and sales*

Under 35 U.S.C. § 102, a patent is invalid "if the invention was known or used by others in this country . . . before the invention thereof by the applicant for patent, or . . . [if] the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent."[9] Defendant Medela argues that clear and convincing evidence shows that prior public use invalidates one or more of the asserted claims of the patents-in-suit. This clear and convincing evidence was the testimony of four witnesses claiming they used the claimed invention before the critical date of the patents-in-suit. According to Medela, Plaintiffs failed to rebut this testimony, thereby warranting judgment as a matter of law as to its invalidity defense.

### *2. Prior art anticipated or made obvious asserted claims*

A patent is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[10] Defendant Medela asserts

9. 35 U.S.C. § 102(a -b) (2002).

10. 35 U.S.C. § 103 (2004).

that the contested claims of the patents-in-suit are invalid because they are obvious. Medela's evidence is two doctors testifying about state-of-the-art wound care in November 1990, and a list of at least seven articles containing prior art references. The doctors testified that various claims in the patents would have been obvious to a person of ordinary skill in the art considering the combination of another patent and any one of these seven prior-art articles. In response to this detailed testimony, Plaintiffs presented "conclusory testimony" of two doctors who had been funded by KCI in the past. According to Defendant Medela, this testimony did not rebut Medela's evidence in any meaningful way, warranting judgment as a matter of law.

*3. New trial including testimony of David Tumey and Marie McGregor*

David Tumey was the head of KCI's Research and Development department and read one of the prior-art articles during his tenure at KCI. The Court disallowed David Tumey's testimony at trial. The Court also prevented the testimony of Marie McGregor regarding her use of prior-art treatments for wounds using negative pressure in combination with dressings.

To determine whether the exclusion of this evidence warrants a new trial, the Court should follow a three-step analysis and assess: (1) the probability that the evidence would have changed the outcome of the trial; (2) whether the evidence could have been discovered earlier through the moving party's due diligence; and

(3) whether the evidence is merely cumulative or impeaching.

*(1) Probability that evidence would have changed the outcome*

Defendant Medela rather conclusively states that had the jury heard Tumey's testimony concerning the similarity of prior art to the claimed inventions, the outcome of the trial would have changed. Similarly, McGregor's testimony is uniquely influential because it concerns her use of negative pressure wound treatment in the late 1980's.

*(2) Whether the evidence could have been discovered earlier through the moving party's due diligence*

Defendant Medela says that KCI failed to disclose the scope of Tumey's knowledge properly such that Tumey's testimony was properly first discovered during trial but before the jury began deliberations. It is not clear when Medela learned of McGregor's testimony.

*(3) Whether the evidence is merely cumulative or impeaching*

Defendant Medela argues this testimony is not cumulative because Tumey has a unique perspective on the prior-art reference. Rather than being cumulative, Tumey's analysis that the prior-art article discloses a device that is at least similar to KCI's patent uniquely

contrasts Plaintiffs' argument that the prior-art article has "nothing to do with our case." Similarly, McGregor's testimony is not cumulative because no one else can testify as to McGregor's personal use.

**B. Plaintiffs' Response**

Plaintiffs respond on two grounds. First, Plaintiffs argue that legally sufficient evidence supports the jury's verdict. As part of this argument, Plaintiffs argue that Defendant Medela's request for judgment as a matter of law must be denied because: (1) Plaintiffs presented compelling evidence of patent validity; (2) Medela's witnesses lacked credibility and credentials; (3) Medela's "public use" evidence lacked requisite specificity and corroboration; and (4) the evidence established that no prior art anticipated or rendered obvious any asserted patent claim. As a second ground for denying Defendant Medela's motion, Plaintiffs contend that the exclusion of Tumey's and McGregor's testimony does not warrant a new trial.

*1. Legally sufficient evidence supports the jury's verdict.*

Plaintiffs couch their argument on the grounds that in this case, the parties presented dueling experts, and it is the jury's responsibility to determine the credibility of the experts. Because Defendant Medela's experts were not credible and compelling, judgment as a matter of law is inappropriate.

*Appendix D*

*(1) Compelling evidence of patent validity.*

Plaintiffs argue that they presented compelling evidence of patent validity. Two doctors explained the invention process, including one doctor who said that Plaintiffs' invention was the greatest advance in plastic surgery in the past ten years. Dr. Orgill also explained the differences between the claimed invention and the prior art. Dr. Orgill is an especially important witness for Plaintiffs, as he received the Court's praise regarding his impressive credentials. Two doctors also testified about the novelty of the claimed invention. This is compelling evidence of patent validity.

*(2) Lack of credibility*

Defendant Medela's witnesses, on the other hand, lacked credibility and credentials, preventing them from meeting the "clear and convincing" burden. Plaintiffs point out that one defense expert had never read a patent and had done no research on negative pressure wound therapy. Additionally, the expert's credibility was impugned by the testimony of BlueSky's founder, who admitted that the patent-in-suit was different than the prior art. Another defense expert lacked credibility because he changed his testimony from one day to the next.

*(3) No collaboration of public use*

Further, Plaintiffs argue that because Defendant Medela's alleged prior public use argument lacks

corroboration, it could not have met the "clear and convincing" standard. A party asserting invalidity based on prior public use must establish that "the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention."[11] Generally, oral testimony of prior public use must be corroborated in order to invalidate a patent.[12] As a result of the distrust of oral testimony, ideal corroboration is evidenced by contemporaneous physical records made at the time of the alleged prior invention.[13]

All four of the doctors required corroboration because they were testifying about their own

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11. *Juicy Whip Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 737 (Fed. Cir. 2002).

12. *Id.* (citing *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1366-68, 51 USPQ2d 1001, 1010-11 (Fed. Cir. 1999)); *The Barbed Wire Patent*, 143 U.S. 275, 284-85 (1892):

> [T]he very fact . . . that almost every important patent, from the cotton gin of Whitney to the one under consideration, has been attacked by the testimony of witnesses who imagined they had made similar discoveries long before the patentee had claimed to have invented his device, has tended to throw a certain amount of discredit upon all that class of evidence, and to demand that it be subjected to the closest scrutiny.

*Id.*

13. *Id.* at 743.

anticipatory activities, but Medela did not produce any corroborating physical records. According to Plaintiffs, the presentation of the photographs and the cross-collaboration of the doctors is insufficient collaboration. In addition to the collaboration argument, Plaintiffs also contend that Medela's witness's earlier use was neither commercial nor public—the negative pressure wound care was experimental and not covered by Medicaid.

*(4) Anticipation and Obviousness*

Plaintiffs' final argument that legally sufficient evidence supports the jury's verdict is that the evidence establishes that no prior art anticipates or renders obvious any asserted patent claim. Specifically, the evidence shows that none of the prior-art references contains all the limitations of any asserted patent claim, such that Medela lacks the clear and convincing evidence necessary to find anticipation of any claim. Moreover, Plaintiffs assert that the record is replete with indicia of nonobviousness.

2. *Exclusion of Tumey and McGregor Testimony*

Apart from their arguments against judgment as a matter of law, Plaintiffs contend that Tumey and McGregor's testimony do not warrant a new trial. First, Tumey's testimony was untimely designated and inadmissible. Defendants met with Tumey as early as 2001. Plaintiffs disclosed Tumey as a person who might have relevant knowledge on December 17, 2004. Fact discovery closed on December 9, 2005, but Medela did

not ask to depose Tumey until after the closing of fact discovery. Despite this late request, the Court allowed Tumey's deposition. Apart from this untimely deposition, Tumey's testimony concerning the similarity of patented inventions is inadmissible because Tumey is not a patent expert, but merely a lay witness.

McGregor's testimony was also properly excluded because it was untimely and uncorroborated. Defendants did not fully disclose the nature of the anticipated testimony until the time of trial. There was also no corroboration of her alleged prior use.

### C. The Court's Decision

Applying the legal standards and upon review of the briefing, the Court finds sufficient evidence to justify the jury's verdict and thus declines to disturb it. The Court finds merit in Plaintiffs' credibility arguments. It is the province of the jury—not the judge—to determine the credibility of witnesses.[14] In such a case as this, wherein highly qualified and devoted counsel represent both sides through a lengthy trial, jurors must wrestle with the credibility of lay and expert witnesses alike, whose juxtaposed opinions are often equally possible but entirely diametric. As such, while it may be true that

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14. *See, e.g., Ray v. Iuka Special Mun. Separate Sch. Dist.*, 51 F.3d 1246, 1251 (5th Cir. 1995) (noting that "the assessment of the witnesses' credibility is clearly a jury function"); *Smith v. Harrah's New Orleans Mgmt. Co.*, No. 05-30096, 2007 WL 98994, at *5 (5th Cir. Jan. 16, 2007) (citing *Hardy v. Wal-Mart Stores, Inc.*, 237 F.3d 632, at *1 (5th Cir. 2000)).

Defendant Medela provided arguably ample evidence of patent invalidity, such evidence carries only the weight as measured by a pool of dedicated jurors.

It is difficult for the Court to assail a verdict such as the one here, wherein the jurors, having been presented with an abundance of evidence, determined that Defendants failed to meet their burden of proof. A reasonable jury was entitled to believe Plaintiffs' evidence and to disbelieve Defendants' evidence if it chose to. In this case, it clearly did so. The Court finds that because the allocation of credibility was within the province of the jury, Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity must be DENIED.

## CONCLUSION

Legally sufficient evidence supports the jury's verdict. Accordingly, the Court DENIES Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity (Docket No. 791). Additionally, to the extent that Defendant BlueSky's Motion for New Trial (Docket No. 797) seeks the same relief as Defendant Medela, Defendant BlueSky's Motion for New Trial is also DENIED.

It is so ORDERED.

Signed this 4th day of April, 2007.

s/ Royal Furgeson
ROYAL FURGESON
UNITED STATES DISTRICT JUDGE

## APPENDIX E — 35 U.S.C. § 103(a)

**§ 103. Conditions for patentability; non-obvious subject matter**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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